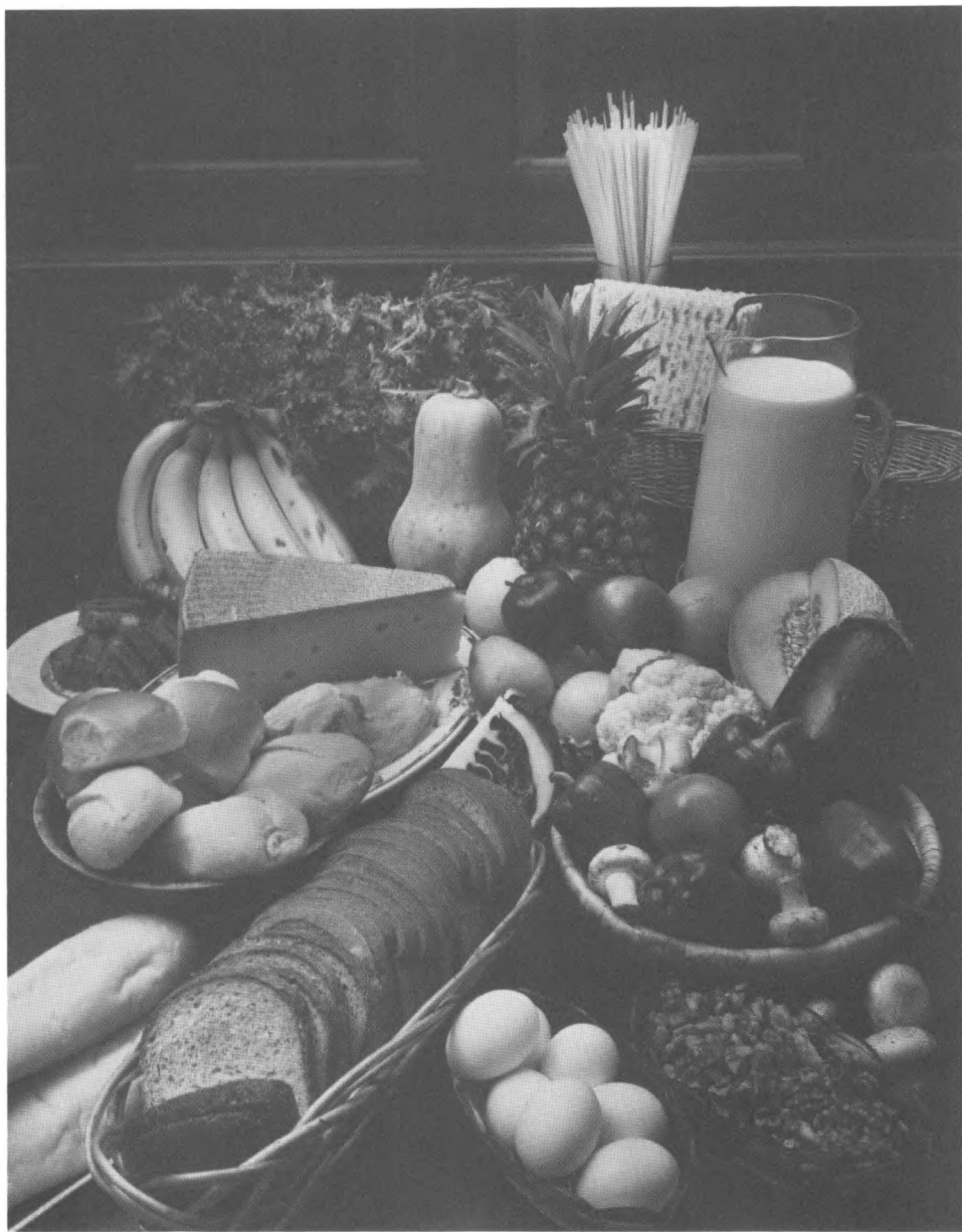
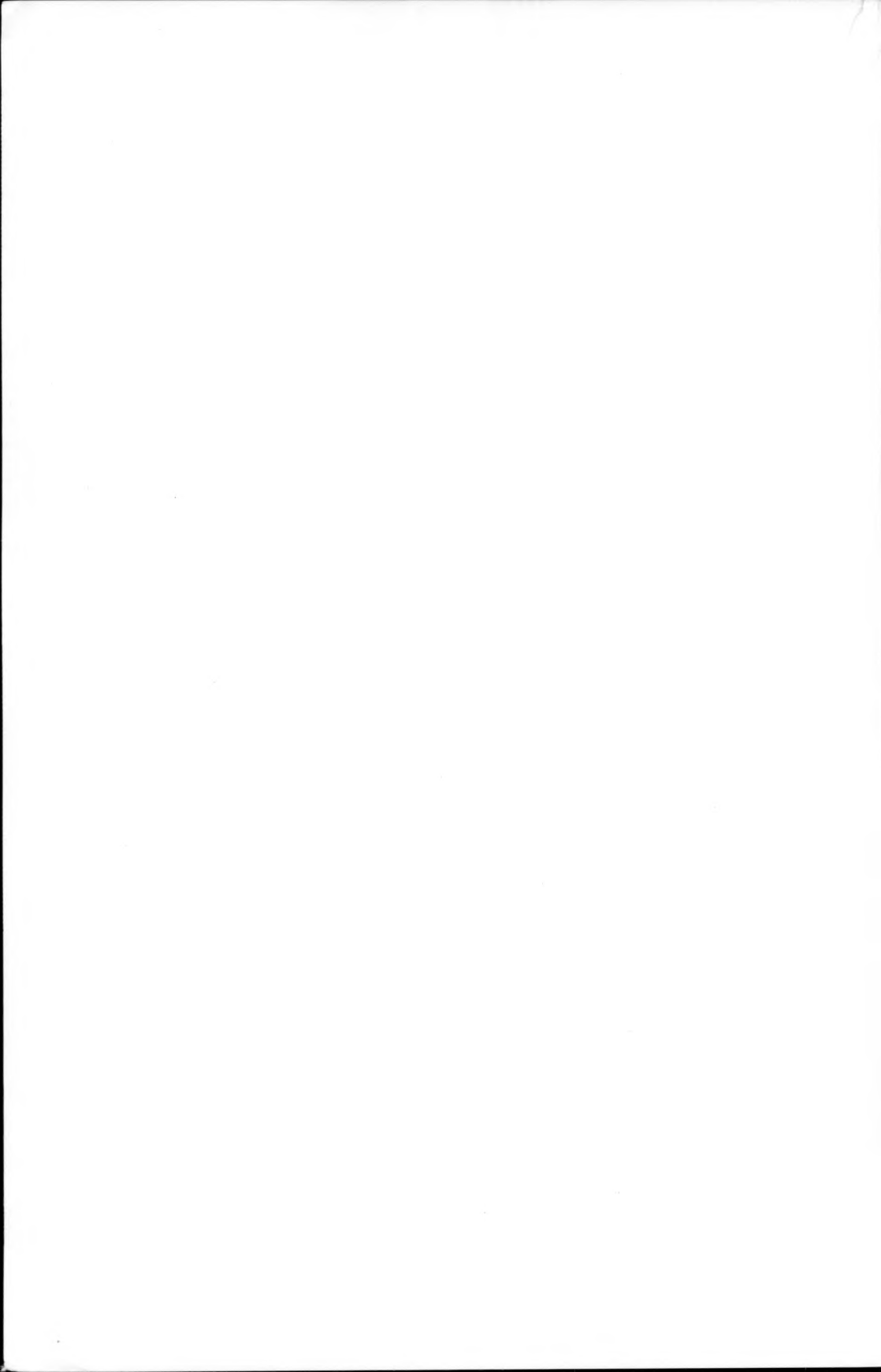


## NABC Report 2

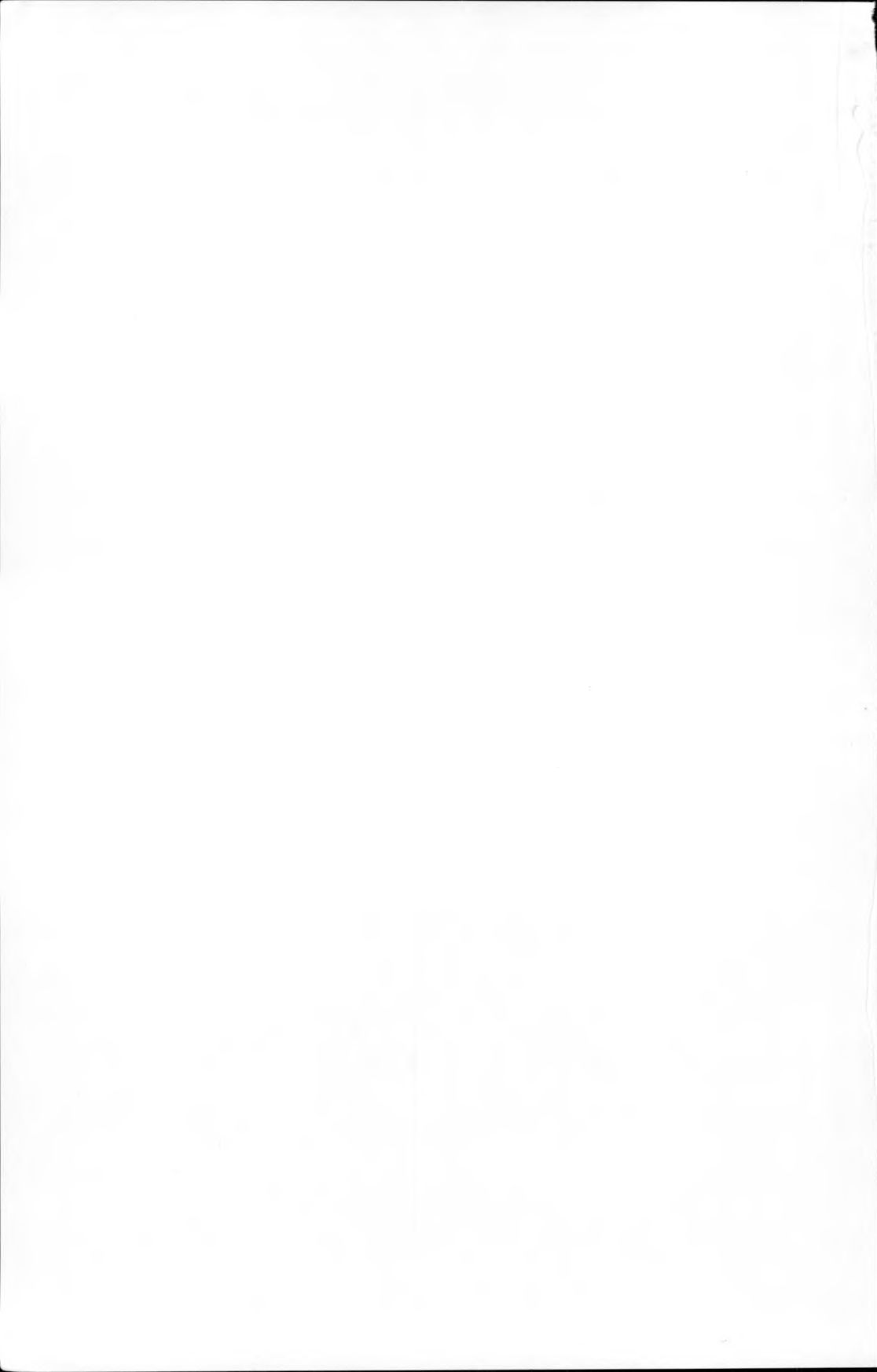


Agricultural Biotechnology, Food Safety and  
Nutritional Quality for the Consumer



# National Agricultural Biotechnology Council Reports





# Agricultural Biotechnology: Food Safety and Nutritional Quality For the Consumer

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**Editor: June Fessenden MacDonald**

NABC Report 2

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## Preface

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In February 1987, responding to the need for a neutral forum for the many interest groups concerned about agricultural biotechnology, Robert B. Nicholas, Esq., McDermott, Will & Emery and Ralph W. F. Hardy, President of the Boyce Thompson Institute for Plant Research, developed the concept of a university/institute consortium concerned with agricultural biotechnology for the benefit of all sectors of society. In January 1988, with initial funding from The Joyce Foundation and the United States Department of Agriculture, the National Agricultural Biotechnology Council was formed representing leading national, not-for-profit agricultural research, extension and educational institutions: The Boyce Thompson Institute, Cornell University, Iowa State University and the University of California at Davis. The Texas A & M University System joined in 1989, giving NABC national regional representation.

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At the June 1990 Council meeting it was unanimously agreed to open NABC membership to other not-for-profit agricultural institutions. Purdue University immediately expressed interest and joined. Several other institutions across the U.S. are currently in the process of joining NABC.

The principal objectives of NABC are to:

- identify issues and public policy questions related to biotechnology in the food and agricultural industries.
- provide a vehicle by which institutions can work together to think about and handle the complex issues surrounding biotechnology and its implica-

- tions for agriculture and agricultural institutions. NABC also strives to create a sense of responsibility, individually and collectively.
- gather and disseminate information, analyses and recommendations to assist practitioners, researchers, administrators, policy makers and other concerned citizens in understanding the many facets to current issues and to ensure the effective and safe development of agricultural biotechnology for the benefit of society.
  - provide a neutral forum for those with differing interests and concerns to come together to speak, to listen, to learn, and to participate in meaningful dialog.

NABC annual meetings, open to all, address timely national issues in areas in which the impact of biotechnology is expected to be high. The first two meetings have demonstrated that those responsible for research, development and policy decisions in universities, state and federal governments and the agribusiness community benefit from a broadened understanding of the issues and policy questions biotechnology poses. One major realization of the Second Annual Meeting was the extent to which all parties in the food area have failed to communicate with each other. The meeting's lecture-workshop format allowed a diverse mix of disciplines and viewpoints, effectively providing a broad range of learning experiences for most participants.

This volume is not a "proceedings" of the Second Annual NABC Meeting, but rather a report communicating the results of the lively workshop discussions and the conclusions and recommendations of the meeting to those outside the immediate areas of agricultural biotechnology and food safety and nutritional quality. Hopefully Parts One and Two will convey the flavor of the meeting and provide a synopsis of the issues identified and the recommendations generated in each workshop.

For more in-depth and specific information, the reader is referred to the plenary addresses (Part Three) and the topical lectures (Part Four). Most are papers prepared by the authors for the meeting, although a few papers were edited from transcriptions of the actual presentations.

It is hoped that this report will contribute to an increased understanding of the diverse viewpoints involved and provide a foundation for addressing many of the concerns about agricultural biotechnology, food safety, nutritional quality and communication among different groups.



## Part One

## Overview

- 12 Summary
- 21 Workshop Recommendations
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- Concluding Remarks



## Summary

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The second annual meeting of the National Agricultural Biotechnology Council (NABC), Agricultural Biotechnology, Food Safety and Nutritional Quality for the Consumer, was held in June, 1990, co-sponsored by the NABC and the Agricultural Research Institute. The selected topic was without doubt a timely one. Increasing media attention given to food safety and food quality has mirrored skyrocketing consumer concerns in this area. In the year of the first United States approval of a genetically-engineered product for use in food production (a microbially produced enzyme for making cheese), the coming of biotechnology to the food arena has not gone unnoticed. One example is the intense public debate that accompanied the introduction of a growth hormone for use in milk production. Genetic engineering techniques provided a plentiful supply of bovine somatotropin (BST), a growth hormone that improves efficiency of milk production in dairy herds. However, the expressed public concern about its use resulted in at least a temporary ban in some parts of Europe, and if approved by the Federal Drug Administration (FDA) it will be initially banned in some parts of the United States.

In its 1990 meeting, the NABC continued to provide a neutral forum for the expression of diverse viewpoints. Here representatives of different interest groups together explored issues related to applications of biotechnology to food quality and food safety, with particular emphasis on consumer perceptions and receptivity. That diverse viewpoints were expressed is documented later in this report in the invited talks and summary reports from the workshops. This opening chapter presents an overview as well as a

### **NABC/JOYCE FELLOWS**

**Candace W. Collmer**  
Boyce Thompson Institute  
with

**Harrison L. Flint**  
Iowa State University  
**Russell C. Parker**  
U California, Davis

### **NABC/JOYCE GRADUATE FELLOWS**

**Cassandra Klotz**  
U California, Davis  
**Johan Swinnen**  
Cornell University

"sense of the body" as a whole that had developed by the closing of the two and a half day meeting.

Through the course of the meeting, participants were presented with specific examples of numerous potential benefits that applications of the "new" biotechnology can bring to food safety and food quality. Biotechnological applications promise a wide range of advances, including leaner meat, enhanced flavor, quality, and processing qualities of foods, more effective monitoring for possible microbial contamination in the current food supply, and reduced pesticide usage on food crops. It is noteworthy that several promises of the past are now products ready for use in food production. The first genetically-engineered, food-grade microbe, a baker's yeast with enhanced leavening properties, has just obtained regulatory approval in Europe. In addition, the FDA has just approved Chymosin as the first product produced by a genetically engineered organism for use in food production. According to Susan Harlander, food microbiologist from the University of Minnesota, Chymosin is "nature identical" to the enzyme rennet which is isolated from calf stomach, but it is purer, in more consistent supply, and microbiologically safer (see Harlander, page 145). There is little disagreement that this represents an advance in both the means and the ends of the production of enzymes useful in food production. The DNA probe technology described by George Parsons, Director of Diagnostics at GeneTrak Systems (see Parsons, page 118), with its increased sensitivity, detects more quickly and earlier in the production process microbial contaminations thereby significantly improving the safety of our food supply.

However, as pointed out repeatedly from the beginning to the end of the meeting, some of the first seeds of the new biotechnology are falling on unexpectedly barren ground. Stated quite simply, society has thus far failed to embrace the scientist's perception of the value of the new biotechnology in the food arena. Given the truly powerful potential of biotechnology to address important consumer concerns about the food we eat, keynote speaker Carol Tucker Foreman, a partner in the consulting firm Foreman and Heidepriem, addressed the question on the minds of many meeting participants: Why aren't the crowds cheering in the streets? Her answers were thought-provoking, and their themes (lack of trust, value conflicts, unequal distribution of benefits and risks, failure to communicate) were reiterated throughout the meeting (See Foreman, page 74).

First, public mistrust of scientific advances is rampant, most probably having been fueled by past experience, when the Better Living Through Chemistry motto of the 1950s saw some products brought to market without ad-

equate prior evaluation. Accordingly, while the promises of DDT, aerosol sprays and nuclear power were acclaimed at the time of their introduction, it was only later, and sometimes much later, that negative impacts were experienced and belatedly acknowledged. As a result, there exists a public concern that biotechnologically-derived food advances also may bring with them unannounced environmental or health risks. "Natural" foods sound more appealing. There is little interest in "new/manufactured" foods unless they can be guaranteed to be safe and healthful.

Secondly, there is a public perception that the risks and benefits of the new biotechnology may be unequally distributed. In such a view, the public bears the (perceived) risks while someone else—the farmers, food processors, scientists or biotechnology companies—gain the benefits (profits). Surprising to many participants, "scientists" are now defined as outside the group of "concerned citizens". On some issues related to biotechnology there exists a true conflict of values among different interest groups. Something that is scientifically sound, and environmentally and nutritionally safe, may have social or economic consequences that are unacceptable to certain segments of the population. Such is certainly the case with the growth hormone BST, once questioned only in terms of milk production efficiency, and animal and consumer safety. The BST debate now is about social and economic conflict and not about science, although the demand for greater and greater proof of safety remains. Yet many participants were surprised at the range of values they shared with other participants identified as being in a different group.

Third, the public appears to have lost confidence in the governmental institutions it once counted on to resolve questions of safety and conflicts between scientific, social, and economic viewpoints. The deregulation of the Reagan era coupled with the scandals in the Environmental Protection Agency (EPA) and other governmental agencies resulted in a loss of faith in the government's ability or desire to protect the public's environment, air, or water, and now, its food supply. The 1990s has a concerned citizenry that has lost faith in the authority figures it once turned to for information and protection. While public confidence is low, Peter Barton Hutt, Esq., a partner at Covington and Burling, when reviewing government regulations related to food safety stressed the adequacy of existing laws to cover biotechnologically-derived foods and food ingredients. (See Hutt, page 154).

Other speakers pointed out that social and demographic issues as well as health and fitness concerns are bringing an additional charge to the food arena. The aging baby-boomers are becoming more concerned with



healthy foods and ever increasing numbers of working mothers demand both fast but also nutritious foods to accommodate changing family lifestyles. These trends are evident in new food marketing strategies where foods for the first time are being differentiated, and successfully marketed, on the basis of safety and quality.

However, the current lack of stringent food labeling guidelines, a scientifically undereducated public, and a loss of faith in traditional "experts" has resulted in a marketplace that is emotional and highly volatile in terms of food issues. Several speakers agreed that the current marketplace is one in which "perception has overtaken fact" in regard to food issues. This is perhaps best documented by studies which show that the public's ranking of various food-related "risks" based on perception of relative danger, is in fact almost perfectly inverted in comparison to a ranking based on actual occurrence of illness or death and scientifically determined "risk factors" (See Pariza, page 167). The obvious, imminent danger of such a climate is that decisions about product acceptability, and regulations for products derived from biotechnology could be made based on such misperceptions rather than on scientifically-derived data about product quality and safety. Lester Crawford, Director of the Food Safety and Inspection Service, United States Department of Agriculture, made clear that safety determinations must be based on science, but science open to public scrutiny (See Crawford and Clarke, page 161).

Over the course of the meeting, it became clear to what a great extent all concerned parties in the food arena have failed to talk with each other, much less communicate. And perhaps because every person in society deals with food on a daily basis, the list of stakeholders or "concerned or involved parties" (the scientific community, the government, and the food industry) have not only failed to listen to the public but have done a poor job in bringing their messages to the citizenry. Not only did scientists and technologists come before the public with misperceptions of the general attitude in present society towards technology, its products, and the institutions that produce and control it, but also their messages were often couched in a "hype" that only tended to rouse suspicions. America's citizenry is not particularly well-educated scientifically and many have found it difficult to understand the science behind the new technologies or simply "tune-out" to science. It is not surprising that what is not understood is feared and/or rejected.

The "hype" needs to be dropped and the whole spectrum of issues related to biotechnology and food needs to be quietly discussed and carefully evaluated. In order to reach meaningful resolution, all voices must be heard. However, all parties must first be "educated" so that a true dialog between all concerned parties, including the consumer, is possible. As stated succinctly in closing remarks by NABC Council member Robert Barker, Cornell University's Senior Provost, "All need to speak, all need to listen, all need to learn" (See Barker, page 27).

Before dialog can begin, all stakeholders need to understand both terms (definitions) and concepts which are currently unfamiliar. For example, the consumer and farmer must learn about scientific technologies to join the discussion with an equal voice. It also must be recognized that consumer opinions, however, varied, must be treated with respect. At the same time, scientists and food producers need to be educated about the relationships between scientific advances and the public interest. They need to assess the impact of "unanticipated effects" of biotechnology and become sensitive to the fact that all scientific advances inevitably change society. While it appears that the implementation of agricultural biotechnology will merely continue the already present trend toward an increasingly technological agricultural system, it does not follow that every new technology should be adopted. It is no longer acceptable to assess the effects of a technology after the fact. Risk assessment, impact assessment and public involvement need to be started early in the research process and continued through to commercialization.

Government regulators also need to be part of these discussions, particularly as the parties struggle to resolve the issue of the degree to which regulations, now based primarily on science, should be informed by social issues. Farmers, too, must come into the dialog. Ann Sorensen, Assistant Director of the Natural and Environmental Resources Division of the American Federation of Farm Bureau, reported on studies that indicated that farmers both need and want to interact with consumers to learn what it is they really want (See Sorensen, page 103). Thus we return full circle to the need for consumer "education" from which the public can better understand about agricultural practices and realistic options (for example, limited pesticide usage versus blemished fruit) so that valid choices can be made.

The economists and marketing people made it clear that it is no longer in question if the consumer will participate in making the choices regarding biotechnology and foods. The consumer has spoken, and will continue

speak, in the marketplace. It became obvious to those in attendance, that the consumer, the farmer, etc. needs to be involved in planning and prioritizing research related to agricultural biotechnology from the earliest stages. It is vital to identify the real concerns of each group, the real parties of action and find real ways to address concerns. Both the benefits and the risks should be discussed and fully assessed. In addition, the consumer needs to understand the technical process of risk assessment currently utilized in the food industry. And scientists, regulators and others need to understand the process of individual and personal risk assessment. Further, all need to distinguish from "zero risk" from "acceptable risk".

One conclusion arising from the NABC meeting is that there exists a pressing need for a "mediating organization" both nationally and at local levels where issues can be examined from many diverse viewpoints in a neutral forum. While "education" of all concerned parties is a prerequisite for such a discussion, it should not be expected to eliminate differences in values among the different groups. The challenges of structuring such a forum are great as some very basic questions at the moment have no answers. For example, who can speak for "the consumer"? Who will establish "the facts"? Do all professionals have vested interests? Given that the values of government regulators, scientists, industry officials, farmers and consumers can be very different, is it possible to find shared values common to all?

While the challenge of consensus building among all concerned parties is great, the consequences of failing to interact and dialog together may even be greater. What could be at stake is the budding agricultural biotechnology area in the United States and its potential to benefit all segments of society. What is possible is an implementation failure due to a lack of public acceptance, not a lack of scientific expertise. The demand for feeding an ever increasing world population coupled with ever increasing stresses on the environment insures that newly developing agricultural biotechnology will be utilized in the world. For example, BST technology was developed in the United States but was first used with government approval in Russia, Czechoslovakia, and our neighbor—Mexico.

Mediating forums are needed where all concerned parties can meet with mutual respect and lowered voices to work together. The forums must consider issues in addition to safety including economic and social ones. Acceptable protocol for evaluation of individual products and processes of agricultural biotechnology need to be developed and periodically revisited. One model for such a protocol may be the updated decision tree presented recently by

the International Food Biotechnology Council (IFBC) and discussed by keynote speaker Ian Munro, Director of the Canadian Centre for Toxicology, for use in safety evaluation of foods derived using genetic modification (see Munro and Hall, page 64). Whole foods, whether biotechnologically-derived or not, and complete diets need to be evaluated for safety.

Keynote speaker Foreman made three proposals for increasing public trust in the area of food-related biotechnology (see page 74). First she suggested that President Bush state clearly that the first priority of government is the health and safety of the American people and that food biotechnology will continue only if it is deemed safe. Second, regulatory procedures related to food biotechnology should be changed to support an active level of public participation including environmental and consumer activists, state and local public officials, and the citizenry at large. Finally, she envisioned a mediating institution where the public could watch individual scientists and individual proponents of food and environmental safety working side by side to find common ground. Such an approach powerfully defuses controversy and tacitly invites the public to join the search for a workable solution to what then becomes a shared problem.

By the close of the two and a half day meeting, the need for a vehicle(s) to foster increased communication about agricultural biotechnology in relation to food safety and nutritional quality was clear. There also surfaced a clear need for all concerned parties to better understand the biological, institutional and social constraints and incentives now facing agricultural biotechnology. Exactly how those concerns will be addressed for the benefit of society is possibly the single most important challenge of the 1990s.



## NABC Special Session

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Following the two and a half day meeting, members of the NABC Council and Operating Committee, NABC Joyce Fellows and Graduate Fellows, AR1 representatives, and workshop chairs and rapporteurs met in two post-meeting sessions to consider the many recommendations brought forth from the workshops and to develop a follow-up strategy for NABC and its member institutions.

Following lively debate, the group collectively developed the following:

I Individual institutions are in a critical position to facilitate the implementation of recommendations at the local/institutional level. While the appropriate focus for NABC is a national one member institutions have state and/or regional orientation.

Z At the national level, the scientific ranking of the food risk list—1) Microbial Contamination, 2) Nutritional Imbalance, 3) Environmental Contaminants, 4) Naturally-occurring Toxicants, 5) Pesticide Residues, and 6) Food Additives—needs to be evaluated by a nationally established group (e.g., National Academy of Science) using clearly defined risk criteria to aid in establishing research needs and setting priorities in the food area with special focus on biotechnology, while recognizing these needs and priorities are continuously evolving.

3 There is general recognition of the need and value of impact assessments when doing science. At the institutional level, social and economic impact should be integrated into the land-grant research and applied development process. Impact assessment is a very substantial undertaking. Land-grant institutions may need to add specific expertise for socioeconomic

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assessments. NABC can play a role in facilitating this with networking among member institutions.

4 There is a need to educate scientists to the value dimension of their work, about impact assessment, public responses to biotechnology and communication with different groups. Individual institutions are in the best position to lead in the education of scientists (public and private), especially during the graduate and post-doctoral training period. At the national level, timely discussion and interactions among different groups should be encouraged at national professional meetings and special conferences.

5 Public sector research is encouraged in areas of special need where it is unlikely others (e.g., industry) will undertake the basic research due to the lack of commercial viability. In particular, research is encouraged into the use of biotechnology 1) to reduce natural toxins and allergens in foods and 2) to create specialty or designed food products for special subpopulations such as those with allergies, or diabetes, or nutritionally-related disorders. Another area identified in need of more research (and funding) is nutrient requirements (e.g., ideal fat intake—how much below 30 percent should it be?) of different groups in the population (e.g., infants, the elderly).

6 A national study on biotechnology relating to safety and nutritional impact of “designer foods” should be commissioned (e.g., a National Research Council study involving the Board on Agriculture and the Food and Nutrition Board).

7 AR1 will develop a Points To Consider document for organizing the scientific information regarding the safety, nutrition and wholesomeness of biotechnologically produced foods and to conceptualize how that information can best be shared with the public as well as interested non-government agencies.

8 There was consensus that the goal of all should be to promote reasoned discourse about agricultural biotechnology in our society among scientists and varied publics recognizing that in a pluralistic democratic society consensus is not always achieved.

## **Workshop Recommendations**

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### **Improving Food Safety Through Biotechnology**

### **Improving Nutritional Quality Through Biotechnology**

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### **Safety of Biotechnologically-Derived Foods and Food Ingredients**

### **Improving Communication on Biotechnology**

Following two days of intense discussion and sometimes vigorous disagreement, participants in each workshop identified several major issues and key topics needing additional research and presented specific recommendations to the entire group on the last morning of the meeting. There was more consensus generated in each workshop than might have been expected given the diversity of each group. Many similarities in the findings and recommendations can be found in the four workshop reports. Summarized here, these reports are presented in full in the next section of this publication, and represent the major contributions of the NABC meeting.

Readers are encouraged to address the issues raised and implement those recommendations relevant to them.

## Improving Food Safety Through Biotechnology

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Procedures to detect and identify pathogens at the earliest possible stages should continue to be developed.

New and rapid methods are needed for detection and identification of naturally-occurring toxicants since the importance and significance of these toxicants will increase as the spectrum of these toxicologic properties is determined.

Need to support research and development efforts to identify genes that regulate and produce naturally-occurring toxicants, allergens and antimetabolites. Molecular genetic technologies should be applied to reduce or minimize risks from these toxicants. There is a need to facilitate detection and identification of contaminants by development of specific, rapid, sensitive and reproducible analytical methods including more efficient, labor-saving and cost-effective testing procedures.

Carefully monitor and evaluate food plants modified by molecular procedures, as is done in traditional plant breeding, so that other properties such as appearance, flavor, texture, aroma, keeping quality, nutrient content and toxicity are not adversely affected.

The food risk—biotechnology matrix (see workshop report page 36 ) should be elaborated further and used to evaluate the efficacy of biotechnology for reducing each food-related risk.

Development of practical and workable standards is a very important aspect of assuring the safety of products derived from biotechnology.

Consumers should be empowered to participate in the process of biotechnology product development through advisory councils and committees, national mediation institutes or other formal structures.

Well-targeted allocation of resources to research—both in the public and private sectors—will provide cost-effective improvements in the safety of the food supply through biotechnology.

Commercial adoption and diffusion of biotechnology products will depend on the risk assessment process, the promulgation of state, federal and scientific standards and how effectively information is shared with the public.



## Improving Nutritional Quality Through Biotechnology

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- The application of biotechnology for improving nutritional quality must be tailored to the specific needs of the target population.
- Food choices by individuals and households are major factors affecting the nutritional quality of diets in the United States which has an abundant, varied, and a highly nutritious food supply. Inappropriate food choices and limited access caused by lack of economic resources result in poor quality diets for many people.
- There are significant limitations in our understanding of the details of the ideal nutritional profile for individuals of different ages, gender, health status, economic status, and genetic makeup. Biotechnology's ability to produce changes currently exceeds our capacity to predict the utility and significance of those changes within our diet.
- Biotechnology has the ability to affect the nutritional profile of major foodstuffs, and thus to improve diets without requiring changes in food choices.
- Entrance into the market of biotechnologically-derived food products could have a secondary impact on nutritional quality by affecting dietary choices. The resulting nutritional impact could be positive or negative, depending on the overall dietary effect.
- Labeling of biotechnologically-derived food products will be an issue of considerable public interest. There should be a mechanism (ideally, a national forum) to debate all sides of this issue and to recommend a national policy.
- Existing regulations appear to be adequate to deal with most issues involving biotechnologically-derived food products and related technical changes in food production and manufacturing in terms of their impacts on nutritional quality.
- High priority should be given to building public knowledge and understanding of biotechnology. The public can then make informed choices which will ease pressure on regulatory and policy agencies.

Biotechnology offers certain advantages over conventional means of enhancing the nutritional quality of foods. However, cost considerations and consumer acceptance of biotechnologically-derived foods must be carefully assessed.

Five highest-priority nutritional quality objectives are:

- 1) Decrease total fat in the diet and improve the fatty acid profile of foods.
- 2) Develop effective nutritional education and consumer information delivery strategies.
- 3) Identify and characterize unintended/unknown nutritional changes that may result from the introduction of biotechnologically-derived foods.
- 4) Develop specific foods with increased or decreased levels of selected nutrients to meet needs of subpopulations with specific nutrient requirements.
- 5) Decrease anti-nutrient content and increase phyto-genic substances of health significance ("protective substances") in foods.

### **Safety of Biotechnologically-Derived Foods and Food Ingredients**

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Each food product, whether or not it involves biotechnology, generates particular safety questions which must be addressed.

The scientific and regulatory communities have the capabilities to evaluate the safety of new food products using existing procedures.

Data requirements for safety decisions—the concept of a decision tree can be used to determine the amount and nature of data that should be required to make assessments about the human safety of biotechnologically-derived foods and food ingredients is endorsed (see workshop report, page 53).

Opportunities for involving the public in dialog on food safety issues should be encouraged.

Post-approval labeling which would allow consumers to make informed decisions needs thorough discussion.

Increased coordination and consistency between federal regulatory agencies is needed and urged.

Harmonization and coordination of state and federal regulatory processes, understanding that harmonization does not necessarily imply standardization, should be undertaken. The federal government should play a leading role in those discussions. There should also be movement towards international harmonization of data requirements, safety standards and regulations.

## **Improving Communication on Biotechnology**

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Acknowledge the legitimacy of a broad set of values. Concerns about the use of biotechnology in food production are not likely to be resolved if all but the most “scientific” perspectives are discounted.

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Promote conversation with more than one voice. A distinction must be made between discussion and monologue.

Discussion about biotechnology is clearly desirable, and should take place in settings where a broad set of perspectives can be aired, considered, and used to guide reasoned human action.

Work towards a national strategy for biotechnology. A forum at the federal level should be established and constituted so as to be broadly representative of the stakeholders in agricultural biotechnology.

Promote discussion about agricultural biotechnology at many levels. Forums for information exchange and discussions should be established at the state and local levels. Credible regional clearinghouses for information about agricultural biotechnology need to be developed.

Encourage communication between the media and researchers. Take steps to train scientists to responsibly handle media inquiries, and reciprocally, to provide opportunities for journalists to increase their knowledge about agricultural biotechnology. Extension units of land-grant universities should be encouraged to further address issues related to biotechnology.

Strengthen all citizens' knowledge about the diverse issues related to biotechnological innovation. Strengthen the teaching of basic bioscience at all levels, the integration of biotechnology into science curricula, and continuing

education for teachers in the areas related to biotechnology.

Acknowledge the importance of effective public relations efforts, but avoid substituting public relations for other communications activities. Stakeholders who use public relations as a tool for shaping public opinion should continually scrutinize the ethics of their efforts.

Promote care and consistency in terminology. A brief but readable glossary of terms would be a useful companion for future meetings, and might also be useful for school teachers, the media and others.

Encourage multidisciplinary research on communications about agriculture-related biotechnology.

**Part Two contains the full text of the four workshop reports.**



## Concluding Remarks

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Let's briefly consider the title of the conference, Agricultural Biotechnology, Food Safety and Nutritional Quality for the Consumer. It is important to realize we are focusing on food safety, nutritional quality and the consumer. We can easily lose that focus, even though we are all consumers.

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One of the reasons for NABC coming into existence was a realization that the world in which we do science, particularly, but not uniquely, agricultural science, is changing. Agricultural science and technology is different than it was 10 or 15 years ago. Biotechnology in particular seems to be resonating in the public mind as very different than other kinds of technologies. NABC tries to bring together the many constituencies concerned with biotechnology impacts so that the issues identified by each can be addressed as we have been doing for the last couple of days.

If we look back at the beginning of public awareness of biotechnology, it was born in hype, which is not the usual way in which science gets started. The majority of the scientists were not responsible for the high public relations profile, but there were quite a few of our colleagues who really pushed the prospects of biotechnology. Wall Street picked it up, and the hype increased. There was talk of the 100 billion dollars of productivity enhancement that was going to occur. Dollar signs were visible in almost everybody's eyes, including those of the biotechnologists. This background is important to keep in mind as we consider the future.

It is also important to note that the public raised a lot of questions about biotechnology that had not been

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raised in the same fashion about basic biological sciences before. For those of us who have been dealing with the commercialization of biological systems (I am not speaking just of biotechnology), or with commercial agriculture, or food production, etc., many of the questions raised seemed illogical. There was even a bit of a wonderment—why are such questions being asked now? What is so different about biotechnology?

The people who do science in agriculture quite rightly perceive themselves as doing science in the public good. Yet they now find themselves defined out of a part of the discussion; no longer part of that group of concerned citizens in which they previously may have placed themselves. By definition, or by difference, agricultural biotechnology scientists are perceived to be in the group that is exploitative and self-interested rather than as workers in the public good. That is part of the new framework in which we, the people concerned with scientific progress and its application to the enhancement of agricultural productivity, must operate.

There are more than scientists and producers involved when dealing with the issues that biotechnology raises. This was a major point raised at this meeting and one each of us must keep in mind. The consumer, the public (consumer and public being interchangeable words here), the regulator, and the legislator are all partners in addressing the issues.

It is quite clear that the sense of this meeting is that dialog is essential, and that all parties in the dialog need "education"—need to be informed. Dialog is not a matter of "us" educating "them". No matter who you are, an "us" or a "them", it must be such that ALL people speak, ALL people listen, and ALL people learn for the dialog to have any value—1) to the participants in it, or 2) to those whose lives may be affected by the decisions and recommendations that come out of the dialog.

There is a need for a mediating organization, (whether NABC can be such an organization is worth talking about, but this should not be a recommendation of this meeting). However, there is definitely a need for an organization which allows the various interested parties (stakeholders) to come as co-equals to the dialog—not as invitees coming to be educated by the organizers. If we can get into a situation where a true dialog can occur, there are some important points to consider:

Who can establish the facts? That may seem like a funny question to ask, but it came up at a conference in March at Cornell that had to do with multicultural education. There may seem to be no connection between that and biotechnology, but one discussion section was about science in relation to multicultural education and different values. An interesting point

was the disagreement as to what the facts of science might be. Does  $2 + 2$  always make four? Establishing the facts of science in these dialogs will be quite important. A current example of this need is seen in the bovine somatotropin (BST) area, it is important to establish as a fact that most of the human race digests BST when consumed in milk or meat—when consumed it is just a readily digestible protein. That may not be the major determinant of acceptance, but it is important to have this digestibility recognized as an established fact in order to move on to other considerations of the use of BST (i.e., a social impact assessment).

Who can speak for the consumer? In the United States there is a profession, the members of which represent the interests of the public and the consumer; and it is separate from the duly elected representatives and their appointees in governmental agencies. This is a very important point to recognize as groups who “represent the consumer” are engaged in dialog and as they identify issues. What is the role of consumer polls? The media? And again, who can be trusted to provide the “right facts” (a redundancy or an oxymoron?) to inform the debate?

Does everyone want to resolve the issues? This point was raised in one of the workshops. As you attempt to have a dialog you need to try to be sure that those who come to the table are genuinely interested in a resolution of issues and finding the best of solutions.

Do all professionals have vested interests?, including professionals in the areas of consumer or environmental advocacy as well as professionals in biotechnology, or in communications, or in marketing or in farming. Do they all have vested interests that we need to understand as we get into a dialog? If these vested interests never get on the table, the dialog can take a very different orientation and have a very different outcome than if all vested interests are recognized and understood by all.

Are there shared values among the participants in any dialog? is another important issue raised at this meeting and one which must be considered as we move ahead in agricultural biotechnology. This question is somewhat different than “Are there vested interests?” Are there shared values? For example, there is the perception that agricultural research in this country has been driven by the concept that increased productivity is good. That is a value. But others who come to the dialog perceive agricultural research to be driven by a desire to improve the quality of food and feed—a different value. It is important to know where those differences are and where the agreements are.

Who can communicate and how to communicate are both important issues. It is important in a dialog that individuals are seen as coming to it openly and that the outcomes are going to be arrived at fairly. So we need to understand better how communication occurs and how people can work toward shared outcomes. We need to learn how to dialog.

Who can evaluate the possible outcomes of biotechnology? The consequences of what a technology is and how it is used? All who are engaged in applying or assessing biotechnology in agriculture need to consider the potentials for unanticipated outcomes from biotechnology. It would be wise, perhaps, to think about everything we do in our life that way, but it is worth stating again here. A real concern that has been raised by both consumers and scientists is whether biotechnology's outcomes will be unanticipated and dreadful. Scientists in particular must recognize that scientific advances do change society and learn to consider outcomes of their science as part of doing sciences; particularly those that generally might be unanticipated.

Even relatively small scientific advances that most people would consider not just benign but actually great improvements, do change society. The concern for what those changes are and whether they are for the best has increased. As an example (which I always present with a little hesitation), the human race did not hesitate to use porcine insulin to affect the consequences of diabetes. Yet the consequences of the development of insulin and its widespread application to control diabetes, in the long term may have a fairly significant impact on the gene pool in the human race. I am not suggesting that we should have made a different decision, but we should understand that there were effects, perhaps unanticipated, that extend well beyond those on the individual treated with insulin.

Even the development of a diagnostic technique could have a social consequence. A diagnostic technique that determines whether or not a plant contains a pathogen eventually may change the economic viability of one farm versus another. That does not mean you do not do the science, but we (speaking of the agricultural colleges and the agricultural experiment stations) have to understand those potential changes and evaluate them as we do the research.

Biotechnology will continue to change agriculture. We must continue to study the changes that have occurred and that are continuously occurring and try to anticipate events that may accelerate change. In particular, we have to anticipate the ways in which biotechnology may accelerate changes across the entire agricultural spectrum from field to supermarket.



The potential benefits of agricultural biotechnology to the consumer are enormous. An important point to keep in mind as we talk about the downsides, the possible hazards and the risks, is that the benefits are enormous. In the areas of food safety alone there will be major positive consequences for the consumer—fewer food contaminants, improved foods for special populations, improved workplace safety, and the elimination of many plant and animal diseases—to name but a few.

There is a difference in perception among stakeholders as to whether enhanced productivity is a good consequence of biotechnology. Agricultural scientists are enhancing productivity in this country; often in commodity areas such as milk where there is already a surplus. The public wrestles with the issue of why should we be doing that? And the intersection between science and the politics of subsidy is real, but it is far from clear that it is understood or used in making policy.

Risks and benefits are not equally distributed. Risks and benefits, both real and perceived, are not only terms which have different meanings to different people, but all too often the risks and the benefits flow to different parties. It is important that assessments of risks and benefits precede technological development and commercialization and be made known to those potentially affected. That has been stated often at this meeting and to the extent it can be done, it should be done.

Agricultural Experiment Stations, Colleges of Agriculture and the USDA have a particular role to play here. Some biotechnological innovations have been assessed, not always successfully, but there have been attempts and there should be more, to make assessments of what may happen if a new technology is put into practice. To go back to a point made at the beginning of the report—the way, the place, and by whom that assessment is done, with all stakeholders involved, might be a role of the mediating organization 1 recommended earlier.

To return to the point of risks and benefits, a point that is important for those of us who come to these issues from a scientific background is that we understand and deal with risks in a technical, probabilistic sense, while the public generally does not. They deal with risk in a personal sense. When asking about risk, what the public really wants are assurances of safety. This is not just a semantic problem, it is a real problem. Can scientists and technologists find a way to convey to the public what they would call “risk” and what the public would understand as a measure of safety?

United States' society has a zero-risk, absolute-safety expectation. For example, in the food area there is a regulation, the Delaney Clause, which requires that food additives or ingredients, if they can cause cancer at any level tested in an animal, not be added to food. The fact that almost all foodstuffs are replete with natural carcinogens has no political significance. It is in this context that any new biotechnological, or any other kind of technological development is considered.

Regulations are the vehicle by which society says what can or cannot be done, and when it can be done. There is a need to resolve the issue of the degree to which regulations are, or should be, informed by scientific and social considerations. Especially in areas of food quality and food safety regulation.

There is also a need to understand why concerns about food hazards are inverted when considering the view of scientists/experts or the public view. If we could understand the differences in concern about real versus perceived food hazards, we would learn a lot about how to communicate effectively in the future about potential risks and hazards.

The public trust in science, in the "Better Living Through Chemistry" approach to the world, as it has in all authorities, has eroded. There is a consumer interest in "natural" things in which greater trust is placed. One of the problems facing biotechnology in the food industry is that when "bio" and "technology" and "food" are linked, it sounds like someone is messing with Mother Nature, and messing with what should be, in the public's view, the most natural thing in the world—Their Food.

To return to a point made before—that is, that the values of the informed groups—the scientists, the producers, the regulators—differ from those of the public. Scientists have to accept that and understand that moving ahead in agricultural technology with the help of biotechnology, is going to increasingly require scientists to be responsive to the public view, and to understand what values they bring to the dialog. Although the point was made earlier, it is worth repeating. The public is diverse. That is a very important point. It is extraordinarily diverse, but so are the other players—scientists, producers, regulators, etc. Although perhaps they are not as diverse in their views and values as the public. Nevertheless, they do differ and it is important to understand that those differences exist.

The public's failure to embrace the scientist's view of the benefits of biotechnology came as a surprise to most scientists. Perhaps a few of the reasons why this might have occurred is that biotechnology, as I said ear-

lier, was born amid a certain level of hype. Scientists engaged in biological research saw biotechnology as a very natural and gradual outcome of earlier work in biochemistry, microbiology and genetics. They did not anticipate either the degree to which it would become a public issue or the negative response of some of the public to it. But again, in understanding how to communicate effectively, scientists need to better understand why public concern has been so strongly expressed.

The public also is skeptical of regulatory agencies and of their commitment to the public good. That also was a surprise to many regulators who have traditionally thought of themselves (in my view quite correctly) as servants of the public good and who find that the public is not necessarily seeing them that way anymore. Regulators and others need to understand why that happened.

Another point—when a technology (or a biotechnology) fails to get implemented, mostly it is not due to the technology being faulty in a technical sense, but rather due to a lack of public acceptance and failure to market (i.e., properly prepare for public acceptance).

The public needs to be involved in planning and prioritizing research as well as in ensuring that appropriate information is made available. Maybe the latter is more important than the former. I would point out that the public is involved through its legislators and other elected officials in deciding what research will get priority (i.e., public funding). But again, that segment of the “public” which does not see itself fully reflected in what legislators and other public agencies do, has to be considered as well as that part of the “public” which does. All stakeholders must be part of the dialog.

Who can represent the public in any dialog?, is really a very important question to be addressed. Also it seems necessary to understand more fully why many, if not most, public agencies especially at the federal level, are not perceived as providing adequate protection of the public interest.

Existing standards and regulations are adequate to provide protection with respect to safety and nutritional value of foods. There will be a need to modify or create new regulations as the world changes. Still, the established modes of changing or creating new regulations are adequate to produce good and effective regulations and guidelines; they just need to be better coordinated and, perhaps, more generally understood.

There is a need to develop protocols for decision-making as has been suggested in the workshops, that are arrived at with consideration of

the different values of different constituencies. Decision trees or protocols that are subject to full scrutiny and revisited regularly, can assure the public that the best possible decisions about risks and benefits are being made.

One final point—the impact of biotechnology, and I would broaden it to include all future technological developments in agriculture (but biotechnology may lead the way), on the traditional structures of research and development in agriculture—the Agricultural Experiment Stations, the Colleges of Agriculture, the USDA, the regional laboratories etc., is likely to be very significant. The relationships between producers of biotechnological products, researchers, the public, the state and public agencies are changing. I urge those of you who direct Agricultural Experiment Stations, (and I wish there were more of you here), to consider that impact. It is an issue deserving consideration. And to keep thinking about it and keep working on it because it would not be in the public good, if the Agricultural Experiment Stations' role in public service is lost because they lost the public trust.



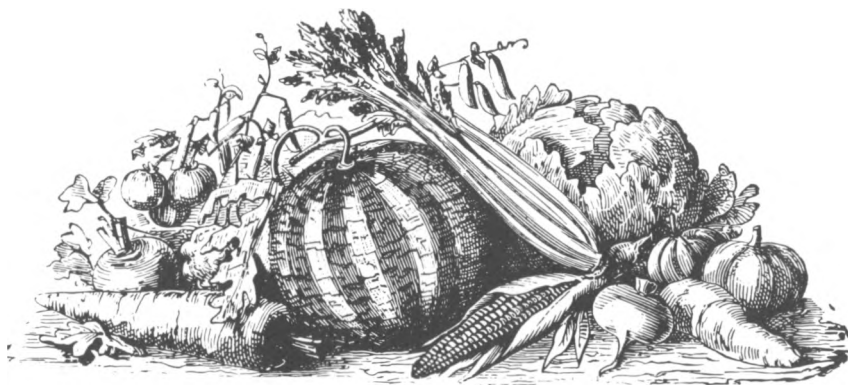
## **Part Two**

## **Workshop Reports**

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## Improving Food Safety Through Biotechnology

The workshop met to discuss the complex issues related to the influence of biotechnology on food safety. The twenty-four workshop participants, who represented a broad spectrum of interests, disciplines and organizations began their deliberations by identifying a long list of important issues.

After considerable discussion of the issues and the direction the workshop would pursue, a matrix that incorporated the major food-related risks and ways that they can be reduced through biotechnology was suggested.

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A matrix for relating food risks to biotechnology  
select one item from each box

risk  
assessment ^

detection  
identification  
reduction  
minimization

source of  
risk ^

pathogenic  
microorganisms  
nutritional concerns  
naturally occurring  
toxigants  
pesticide residues  
food additives

product  
of interest ^

plant  
animal  
microbial  
biomolecular

levels of the  
food system

production  
processing  
distribution

For example:

Would it be productive to do biotechnology research on the  
detection of naturally occurring  
toxigants in plants at the processing

stagei

This food risk—biotechnology matrix provides a description of where each food-related risk can be quantified in plant, animal and microbial food products in each segment of the food chain. The purpose of the matrix is to identify all the key components that need to be addressed and establish the most pro-

ductive direction of biotechnological research for ensuring the safety of the food supply.

### **Source of Risk**

After discussing the matrix, workshop participants then addressed each source of risk and expanded on ways that biotechnology could be used to reduce these risks and improve food safety.

**Pathogenic Microorganisms** Since pathogenic microorganisms are considered by many scientists to be the source of greatest risk in food products, a major thrust of research should be the development of techniques to detect, identify, reduce, and minimize the presence of these organisms.

For detection and identification of pathogens in all food products at all levels of the food chain, DNA probe assays and immunoassays continue to be enormously beneficial to manufacturers, processors and consumers. These methods are not only faster, more sensitive and accurate than traditional testing procedures, but are more cost-effective. In the future, automated systems will be available for detecting and identifying pathogenic organisms. For example, biotechnological procedures for the amplification of DNA (PCR, LCR and Q Beta assays) are currently under development. The workshop group stressed that procedures to detect and identify pathogens at the earliest possible stages of food production and processing should continue to be developed.

To reduce and minimize food pathogens in food production, the group suggested that immunization in the form of subunit vaccines for animals, preproduction environmental/source testing and the possible modification of the intestinal flora of animals be considered to reduce and minimize the types and numbers of pathogens present.

In food processing plants, in-line safety assessments and assurances can be obtained with genetically engineered biosensors, "dip stick" diagnostics, and antimicrobials developed through biotechnology. These methods are especially useful as monitoring tools in processing plants that utilize the Hazard Analysis Critical Control Point concept as part of their product safety system.

In the food distribution system, the use of "dip stick" diagnostics to detect the presence of pathogens, time/temperature abuse indicator systems, and microbial biosensors would provide another level of product safety assurance.

**Nutritional Concerns** Since another workshop was given the task of developing information on improving nutritional quality of foods through biotechnology, our group did not address this issue.

**Naturally Occurring Toxicants** The naturally occurring sub-chronic and chronic toxins, allergens and antimetabolites that are contaminants in many common foods are another food-related risk. The importance and significance of these toxicants will increase as the spectrum of these toxicologic properties is determined, so new, rapid methods are needed for their detection and identification.

Foods derived from plant, animal and microbial sources all have the potential to contain naturally occurring toxicants. Although the biotechnology research base is small, the workshop group felt that the development of diagnostic assays for the detection and identification of naturally occurring toxic chemicals especially during food production is needed.

Molecular genetic technologies should be applied to reduce or minimize risks from naturally occurring toxicants. These approaches may include deletion of genes, inactivation of gene expression or antisense methods.

Each of these approaches could yield plants that are free of the natural toxin, allergen or antimetabolite. This area may be a major opportunity for biotechnology to improve food safety.

As an example, mycotoxins pose multiple risks because of their carcinogenic and immunosuppressive properties. In addition to developing detection systems for mycotoxins, researchers are currently trying to produce highly field-competitive *Aspergillus* strains that lack the ability to produce aflatoxin. The objective is to develop a biological control agent that reduces the likelihood of aflatoxin contamination.

While there are major research opportunities in this area, there are some limitations with these genetic manipulations and culture techniques. The plant's susceptibility to insects, disease, drought, and other environmental conditions could be affected. Genetically-altered "toxin free" animals and microbes might also be adversely affected. A major limitation is the possibility of public resistance to the release of genetically altered microorganisms into the environment.

There is a real need to support research and development efforts to identify genes that regulate and produce naturally-occurring toxicants.

**Contaminants** Contaminants in the environment represent another food related risk. These contaminants range from nitrate contamination of water supplies to the accumulation of heavy metals in plants and are usually the result of human error. They need to be rapidly detected and identified to minimize the risks to humans. All food products, at all levels of the food chain, are susceptible to chemical contamination.



To facilitate detection and identification of contaminants, attention needs to be focused on the development of specific, rapid, sensitive, and reproducible analytical methods including more efficient, labor-saving and cost-effective testing procedures.

Techniques of biotechnology have limited applications in the reduction or minimization of contaminants, however plant biosensors could possibly be used to detect physiological changes resulting from contamination.

**Pesticide Residues** Although the risks due to synthetic pesticide residues in foods are not rated highly by scientists, they are as perceived by the public as very important. Biotechnology can be used to reduce the usage of pesticides in production agriculture, food processing and food distribution. Current methods to detect and quantify residues on raw agricultural products and processed foods are sensitive and accurate, but require sophisticated laboratory instrumentation and expertise. Genetically modified biocontrols have the potential to reduce and minimize the types and amounts of pesticides used in plant and animal agriculture. Genes for the microbial insect toxin from *Bacillus thuringiensis* have been incorporated into plants to protect them from insect pests. Genes for coat proteins of plant viruses have also been incorporated into plants and protect these transgenic plants from viral infection. This plant genetic modification research by molecular processes must be carefully monitored and evaluated, as is done in traditional plant breeding, so that other properties of the foods, such as appearance, flavor, texture, aroma, keeping quality, nutrient content and toxicity are not adversely affected.

**Food Additives** Although the detection and identification of food additives are not significant problems, many consumers prefer foods that are as natural and "additive-free" as possible. Processed foods of plant, animal and microbial origins often use direct additives such as preservatives, colors, flavors, flavor enhancers, emulsifiers, stabilizers, thickness, texturizers, leavening agents, humectants, and anti-caking agents.

Biotechnology is currently being used in the production of acidulants, antimicrobial preservatives, vitamins, thickeners, flavors and many other food ingredients. In addition, genetic manipulation of food-grade microorganisms has improved the fermentation of dairy, meat and alcohol products.

In the future, biotechnology research may provide genetically-altered food-grade organisms capable of surviving in the gastrointestinal tract that can protect animals, or even humans, from invasion by pathogenic organisms.

All of these techniques are aimed at improving or maintaining the nutritional value, quality, and safety of foods, while enhancing consumer acceptance and facilitating food preparation. If, through biotechnology, food ingredients and additives can be produced more efficiently and function more effectively, then a reduction in the use of additives is possible.

Indirect food additives, such as residues of veterinary drugs in food, occur in animal products and originate during food production. Techniques of biotechnology, particularly immunoassays, can be used to detect and identify residues through quick and inexpensive on-farm screening tests. In addition, minimization and reduction of risks from drug residues can be achieved through the development of new-generation veterinary drugs from biotechnology that are effective yet leave no harmful residues.

The workshop recommends that the matrix presented above be further elaborated and used to evaluate the efficacy of reducing each food-related risk through biotechnology.

### **Limitations to Research and Development**

Workshop participants also recognized and discussed the limitations that can impede the research and development of biotechnology. These limitations include the broad policy issues of standards, consumer communications, as well as the development, adoption and diffusion of technology. Each area is summarized below.

**Standards** There is a lack of scientific standards for the products of biotechnology, including reference standards for product/process efficacy, federal regulatory standards (including an organized framework for product approval and utilization) and advertising standards for products being sold to others. This lack of standards tends to erode consumer confidence in the safety of biotechnologically derived products as well as continues to reinforce the many negative impressions associated with this emerging field of technology. Development of practical and workable standards is a very important aspect of assuring the safety of products derived from biotechnology.

**Consumer Communications** Scientists have not adequately articulated the risks and benefits associated with the products of biotechnology to the public. Involving the public in the decision-making process and communicating this information to consumers in an understandable and unbiased manner are also integral concerns of this workshop. The group felt that consumers should be empowered to participate in the process of biotechnology product development through advisory councils and

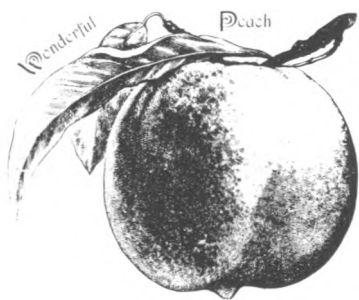
committees, national mediation institutes or other formal structures. Early dialogue is very important in assuring that safety concerns are effectively being addressed.

**Adoption and Diffusion of Technology** The commercial adoption of products derived from biotechnology and the development and diffusion of biotechnologies will depend upon the risk assessment process, the promulgation of state, federal and scientific standards and how effectively information is shared with and communicated to the public. If products and technologies are developed that have not carefully and adequately addressed these three areas of concern, then commercial adoption and diffusion of these technologies will be limited.

Priorities and incentives for future research, development and commercialization will certainly be driven by economics. New products and processes will emerge in the areas with both perceived need and large markets.

The workshop concluded that the well-targeted allocation of resources to research—both in the public and private sectors—will provide cost-effective improvements in the safety of the food supply through biotechnology.

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## Improving Nutritional Quality Through Biotechnology

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### Introduction

There is general agreement among nutritionists that individuals with access to an abundant and varied food supply can select a nutritionally adequate diet from available foods, provided they make appropriate food choices. To promote health and prevent disease, the U.S. Departments of Agriculture and Health and Human Services have issued Dietary Guidelines for Americans (USDA, HHS, 1985) to assist consumers with food choices. These seven dietary guidelines recommend eating a variety of foods; maintaining desirable weight; avoiding too much fat, saturated fat, and cholesterol; eating foods with adequate starch and fiber; avoiding too much sugar; avoiding too much sodium; and moderate drinking for those who choose to drink.

While these guidelines address some of the major nutritional concerns in the U.S., for much of the rest of the world inadequate intakes of calories, protein, and certain vitamins and minerals are major problems. Therefore, the application of biotechnology for improving nutritional quality must be tailored to the specific needs of the target population.

### Procedure

The workshop group discussion began by settling on a definition of nutritional quality. The definition used by the group was as follows:

Nutritional quality of foods and diets is defined by the content of essential nutrients and other components needed for health. Diets of high nutritional quality provide nutrients and other factors in optimal amounts and proportions for achieving and maintaining good

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health. The nutritional needs of all individuals or subpopulations are not necessarily the same. The nutritional quality of individual foods is best considered in the context of the overall diet and with respect to traditional foods.

Based on this definition, key objectives for improving nutritional quality of foods and diet were identified. These objectives, in descending order of importance according to an anonymous vote of the workshop participants, were: 1) Decrease total fat in the diet and improve the fatty acid profile of foods, 2) Develop effective nutrition education and consumer information delivery strategies, 3) Identify and characterize unintended/unknown nutritional changes that may result from the introduction of biotechnologically-derived foods, 4) Develop specific foods with increased or decreased levels of selected nutrients to meet needs of subpopulations with special nutrient requirements and 5) Decrease antinutrient content and increase phytochemical substances of health significance ("protective substances") in foods.

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The workshop group then proceeded to a discussion of these five highest-priority nutritional quality objectives. These discussions led to two types of results or conclusions which are summarized in the two main parts of this report. First, several of the findings of the group's discussions are quite general in nature. These general findings constitute the first segment of this report. Second, the report includes a summary of the results relating to the five highest-priority objectives discussed by the workshop group. Each of the five high-priority objectives, except for that pertaining to nutrition education and consumer information is discussed with a common format, in which the following matters are treated: (a) technical feasibility of biotechnology having a significant impact (b) importance of the objective as a public health/consumer issue, (c) advantages and disadvantages for pursuing this priority with the use of biotechnology (d) recommendations for policy, and (e) recommendations on research priorities.

### **General Findings**

1. The United States has an abundant, varied and a highly nutritious food supply. However, inappropriate food choices and limited access caused by lack of economic resources results in poor quality diets for many people.
2. Food choices by individuals and households are the major factor affecting the nutritional quality of diets in the United States.

3. Nutritional goals can be achieved simply by consumers exercising sound food choices among currently-available products, i.e., without the intervention of biotechnology, chemical engineering, food engineering, or any other advanced technology. The importance of food choice highlights the important role that nutrition education and consumer information must play.
4. There are significant limitations in our understanding of the details of the ideal nutritional profile for individuals of different ages, genders, health status, economic status, and genetic make-up. The ability of biotechnology to produce changes currently exceeds our capacity to predict the utility and significance of those changes within our diet.
5. Biotechnology has the ability to affect the nutritional profile of major foodstuffs, and through this to improve diets without requiring changes in food choices.
6. Entrance into the market of biotechnologically-derived food products could have a secondary impact on nutritional quality by affecting dietary choices. These biotechnologically-derived products may be more or less attractive and therefore may replace other "traditional" food items. The resulting nutritional impact could be positive or negative, depending on the overall dietary effect.
7. Labeling of biotechnologically-derived food products will be an issue of considerable public interest. There should be a mechanism (ideally, a national forum) to debate all sides of this issue and to recommend a national policy.
8. Existing regulations appear to be adequate to deal with most issues involving biotechnologically-derived food products and related technical changes in food production and manufacturing in terms of their impacts on nutritional quality. However, new regulations in the areas of nutrition labeling and food composition analysis may be required.
9. Current public mistrust of nutritional information (especially from the scientific community and private firms) and public concerns about biotechnology will combine to produce difficult environment for settling policy and regulatory issues. High priority should be given to building public knowledge and understanding of biotechnology. The public can then make informed choices which will ease pressure on regulatory and policy agencies.
10. In general, biotechnology offers certain advantages over conventional means of enhancing the nutritional quality of foods. However, cost con-

siderations and consumer acceptance of biotechnologically-derived foods must be carefully assessed.

## **Objectives for Improving Nutritional Quality Through Biotechnology**

- I. Decrease total fat in the diet and improve the fatty acid profile of foods.

### **Background**

Americans on average ingest 37 percent of their total calories from fat. It is widely accepted that this percentage should be reduced to 30 percent of calories or less. High fat diets are associated with a variety of chronic diseases. For this reason the fat content of foods and of the “national diet” are primary considerations relating to nutritional quality.

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### **Feasibility**

1. It was judged to be highly feasible that:
  - a. Through the use of growth regulators such as BST/PST, growth hormone releasing factors, and beta-agonists in the swine and beef industries, a 2 to 3 percent aggregate reduction in the fat content of the diet could be achieved.
  - b. Through plant breeding or changes in processing techniques soybean and corn oils could be modified in their fatty acid composition so as to achieve a more nutritionally favorable fatty acid profile.
2. The use of biotechnology to lower the cholesterol content of foods, while feasible, is unlikely to have a significant impact of serum cholesterol levels or heart disease risk.

### **Importance**

The overall importance of decreasing total fat in the diet is very high. Lowering fat content of the diet is likely to lower chronic disease risk. Altering the fatty acid profile of dietary fats may also yield a health benefit.

### **Advantages and Disadvantages**

#### **1. Advantages**

- a. Increasing the availability of low fat animal products could result in reduced fat intakes with little or not change in food habits.
- b. There are cost-efficiency, resource-use efficiency (water and energy), and international competitiveness gains as well as nutritional quality advantages of using growth hormones in livestock production. The estimated 30 percent reduction in costs to farmers would likely be largely passed on to the consumer.

c. A decrease in fat (and, hence, in calorie) content of foods may reduce the high prevalence of obesity.

d. Reduction of fat intake and changes in fatty acid profiles may decrease risk of heart disease and cancer.

## 2. Disadvantages

a. If decreases in the fat composition of meat leads to an increase in protein intake, health consequences associated with excessive protein intakes might increase in susceptible individuals.

b. The scientific community is yet uncertain about what the optimal fatty acid composition of the diet should be.

c. As with the example of aspartame (a sugar substitute) which despite widespread use has not led to the decreased consumption of sugars or lower prevalences of obesity, the availability of lower-fat foods may not result in reduction in fat intake or improved health status.

## Policy Recommendations

1. There should be changes in the marketing system (particularly in grading systems and in nutritional labeling) to support nutritional change. Quality grades for beef are currently based on fat content, such that fatter animals command higher prices for the farmer. The grading system should be based on protein or some other component(s). In general, there should be a "value-based marketing system," in which prices received by farmers from "first handlers" would be proportional to nutritional quality.
2. There is a need for a mechanism to review and recommend policy having to do with the labeling of food as "biotechnology-derived" foods.
3. Agencies and regulations for controlling altered foods are already in place.

## Research Recommendations:

1. Develop better methods for determining the composition of food products—particularly rapid methods for determining fat composition of live animals as well as the fat and fatty acid composition of carcasses and retail cuts.
2. Develop and implement a value-based market system.
3. More accurately determine fat intakes by individuals and subpopulations and improve understanding of relationships between dietary fat and disease risk.
4. Elucidate mechanisms of regulation of plant and animal growth.
5. Identify unintended or unknown changes (biological, physical, sensory changes) in products resulting from the application of biotechnology.



## II. Develop Effective Nutrition Education and Consumer Information Delivery Strategies.

### Background

Given the overriding importance of dietary choices in determining the nutritional quality of diets, nutrition education and consumer information remain vital. The growing importance of biotechnologically-derived foods will add new dimensions to nutrition education and consumer information.

### Recommendations

1. Nutrition education and consumer information must deal with both perceptions and realities. Several questions must be addressed in order to develop effective strategies:
  - a. What does the consumer need and/or want to know?
  - b. What information should be on food labels? How can consumer comprehension of the information on labels be improved?
  - c. Who should be responsible for nutrition education and information? (Industry may not be a good choice due to possible conflicts of interest.)
2. Education should begin early and continue throughout life in order to affect behavior.
  - a. The science curriculum in elementary and secondary schools should be strengthened so that graduates will be prepared to understand and evaluate complex technological issues.
  - b. Teaching materials dealing with nutrition and food science should be developed and made available to elementary and secondary school teachers.
3. Scientists should make efforts to communicate their findings to the consumer. Scientists need to be more aware of consumer needs and perceptions and be prepared to dispel misperceptions and misinformation in an unbiased manner.
4. Food advertising should be carefully designed to avoid misleading and exaggerated claims about diet and health. "Marketing with Integrity" should be the motto of all ad agencies with food accounts.

### III. Identify and characterize unintended/unknown nutritional changes that may result from the introduction of biotechnologically-derived foods.

#### Background

As with any intervention in the food system, the introduction of biotechnologically-derived foods have may unintended and/or unknown impacts on nutritional quality. There is a need to better understand the nutritional effects of altering food composition whether by conventional means or means of biotechnology. For example, genetic alterations of plants may affect nutrient interactions, nutritional bioavailability, vitamin potency, levels of antinutrients, etc.

#### Feasibility

Biotechnology could be a powerful and feasible tool for evaluating composition of food, and hence can help in monitoring.

#### Importance

1. Public health importance is potentially great. For example, there will be a growing emphasis on "engineering" of plants to produce higher levels of naturally-occurring toxicants to control pests, and it will be important to determine whether these toxicants make their way into the food supply and/or whether they will have adverse impacts on nutritional quality and health.
2. Monitoring of new foods (by comparison with the reference standard of old or "traditional" foods) can help to maintain the nutritional quality of the food supply.
3. Since the significance of any single food to overall nutrition is low in the industrialized countries, unintended changes in one food are not likely to have major effects on overall nutritional quality. In low-income countries, however, a single food may have a major impact on the nutritional quality of the diet.

#### Advantages and Disadvantages

##### 1. Advantages

- a. Monitoring of nutritional changes will ensure that there are "no surprises".
- b. If these data are routinely collected, it could speed up regulatory approval processes.

##### 2. Disadvantages

- a. Excessive monitoring and assessment requirements for biotechnologically-derived foods may lead to prohibitive product development costs.

## Policy Recommendations

1. Regulatory guidelines are in place and are reasonable. The current “10 percent” FDA guidelines (that there should be scrutiny of new foods in which there is a 10 percent or greater departure from the “parent,” “reference,” or “traditional” food in any nutritional parameter) is reasonable.
2. While changes in concentration of nutrients are relatively easy to monitor, changes in the bioavailability of nutrients are much more difficult to measure. Additional regulatory guidelines governing bioavailability may be necessary.
3. Nutrition labeling regulations should be revised and should specifically address the issue of “new foods.”

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## Research Recommendations:

1. Develop improved methods for measuring the nutrient composition of foods.
  2. Develop improved methods for assessing nutrient interactions and nutritional bioavailability.
- IV. Develop Specific Foods with Increased or Decreased Levels of Selected Nutrients to Meet Needs of Subpopulations with Specific Nutrient Requirements

## Background

While for the majority of Americans the food supply is abundant and safe, there are some specific subpopulations, particularly infants, the elderly, and other persons at high risk of disease, for whom foods with particular nutrient characteristics may make a major contribution to their well-being. Altering the levels of selected nutrients (e.g., beta-carotene) in foods may have especially widespread benefits in low-income countries where a small number of foods account for a large share of food intake.

## Feasibility

Biotechnology could significantly affect several specific foods. For example:

1. Biotechnology could contribute to the development of high-protein grains and improve amino acid balance in staple foods of the Third World.
2. Improved infant formula products (simulated breast milk) could provide major benefits to infants who cannot be breast fed or who require special diets as a result of allergies or metabolic abnormalities.

3. Availability of new or altered plants may lead to increased variety in diets.
4. Specialty foods for individuals with allergies, lactose intolerance, diabetes, etc., are now feasible through biotechnology.

#### Public health importance

1. Internationally, public health importance is high.
2. In the U.S., the public health importance is low, since, in general, the population is already relatively well-nourished.
3. For particular subgroups in the U.S. (e.g., infants, persons with lactose intolerance), however, the importance may be very high.

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#### Advantages and Disadvantages

##### 1. Advantages

- a. Increasing the nutrient content of selected foods may decrease risk of nutritional deficiencies.
- b. Appropriately designed foods may improve treatment of patients with nutritionally-related disorders.
- c. These foods may allow improvement of nutritional quality of diets with little or no change in food habits since the foods should be similar to traditional foods in organoleptic qualities.
- d. These foods may reduce the need for nutrient fortification and supplementation since nutrient levels could be increased through genetic manipulation of the plant or animal.

##### 2. Disadvantages

- a. It is difficult to predict the overall impact of many of these changes; in fact, in some cases the impact might be negligible or negative.
- b. Interventions to increase or decrease selected nutrients may lead to adverse changes in sensory characteristics of food. Other solutions to poor nutritional quality (such as improved nutrition education) may be more efficacious.
- c. There should be caution not to view these methods as a panacea.

#### Policy Recommendations

1. Many of these products will be similar to "orphan drugs" and thus not cost effective for companies to develop. There will a need for alternative means (e.g. government funding) for developing several of these technologies.
2. Delivery systems must be targeted to the appropriate subpopulations or subgroups.

### Research Recommendations:

1. Evaluate consumer reaction to modified products (both global and domestic).
  2. Determine if the application of these methods is practical. In some cases, conventional applications may be less costly and more effective at accomplishing the task at hand.
  3. Increase understanding of plant metabolism to determine the nature of the biochemical pathways that affect the nutrient composition and nutrient bioavailability of foods. Currently, these pathways are not well understood.
- V. Decrease antinutrient content and increase phytochemical substances of health significance ("protective substances") in foods.

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### Background

Many constituents of foods are known or suspected to be "antinutrients" or "protective substances". Examples of antinutrients are goitrogens, trypsin inhibitor, oxalic acid, and gossypol. Examples of "protective substances" are anti-carcinogenic substances (phytoestrogens, flavonoids, and other antioxidants).

### Feasibility

In general, it seems relatively feasible to use biotechnology processes to decrease antinutrients and increase protective substances.

### Public Health Importance

1. Internationally, the importance is potentially high.
2. In the U.S., the importance is low for antinutrients, and potentially high for protective substances.

### Advantages and Disadvantages

1. Advantages
  - a. Increased levels of certain protective substances may reduce cancer risk.
  - b. Reduction in certain antinutrients may improve the bioavailability of nutrients.
  - c. Reduction of antinutrients may make previously inedible foods available for food utilization.
  - d. Removal of antinutrients by biotechnology means may reduce processing costs since the objective of some current processes is to inactivate antinutrients.

## 2. Disadvantages

- a. Modifications could decrease the acceptability of some foods.
- b. Modified foods may require redesign of processing procedures.
- c. There is the potential for "overages" in some substances that might be harmful, and thus there is a need to monitor these alterations closely. It is possible to have too much of a good thing.

## Policy Recommendations

There is a need for a regulatory definition of new foods ("designer foods") so that it can be known precisely when a food is to be treated in the regulatory processes as a food or as a drug.

## Research Recommendations:

Identify active phtogenic components and their mechanisms of action in foods, and to find the safe and adequate range of various substances.

## Reference

United States Department of Agriculture, U.S. Department of Health and Human Services, Nutrition and Your Health: Dietary Guidelines for Americans, Second Edition, Home and Garden Bulletin Number 232, Washington, DC: USDA, 1985.



## Safety of Biotechnologically-Derived Foods and Food Ingredients

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The workshop's first challenge was to identify different issues related to the safety of biotechnologically-derived foods and ingredients. Initial discussion identified approximately 50 issues considered important and relevant—issues as diverse as the participant's backgrounds, ranging from questions about particular aspects of the genetic engineering process to concerns about implications for the current food safety and regulatory system, including a consideration of the social and economic impact of these safety issues for relevant industries, their workers, and consumers. These issues were prioritized into the following clusters of concern: Safety Considerations; Regulations and Decision-Making; Data and Research; Consumer Consideration; Environmental Consideration; and Produce Issues in the Appendix, page 56.

The discussions on these issues raised two major questions which continued to surface throughout the workshop: One, the relationship between issues of food safety to biotechnology. Two, whether issues should relate exclusively to products or processes.

The question of whether biotechnologically-derived foods present any unique safety considerations was debated extensively. If so, would they require changes in the current regulatory system? And furthermore, does the entire existing regulatory and assessment process need to be revised, or even overhauled? Intertwined was the question of whether safety assessments should include the process or focus exclusively on the product. A notable line of thought emerging from the discussion was that a “scientific” or “technical” assessment does not account for potential conceptual differences of

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unique safety considerations which may exist for biotechnologically-derived products. It was agreed that there is nothing unique about biotechnologically-developed foods or food ingredients and that existing regulatory, assessment, and legislative systems are sufficient to safely regulate new technologies.

However, when the discussion broadened to include areas such as consumer concerns, the group recognized that biotechnologically-derived products are perceived to have unique features.

The workshop developed the following statements and recommendations:

1. Each food product, whether or not it involves biotechnology, generates particular safety questions which must be addressed.
2. Molecular biotechnology is a process which can produce new food products, however, the scientific and regulatory communities have the capabilities to evaluate the safety of these products using existing procedures.
3. It was felt that safety assessment should focus on the product, not the process. Further, no unique safety considerations were deemed to be needed for biotechnology products, although there is a need to be alert to possible undesirable changes (e.g., increases in a natural toxin).

A critical need to establish what kind and how much data should be required for a safety assessment was recognized by the group and actively debated. Questions such as "Which kind of information and how much of it is required for safety assessment? What is the time frame for data collection? Who does it? Who funds it?" drove the discussion. A proposal to endorse the decision trees in the recent International Food Biotechnology Council (IFBC) report was not supported because few participants were sufficiently familiar with the report to judge its quality. However, the concept of a decision tree was approved and with it a number of topics that should be addressed in food safety evaluations.

Participants endorsed the concept of a decision tree as a guide to determine the amount and nature of data that should be required to make assessment about the human safety of biotechnologically-derived food and food ingredients. The following types of information should be considered in food safety evaluations:

- i) composition of final products and the biological safety of the components of the food;
- ii) the genetic system: donor system; vector; and host expression system;



- iii) target animal safety;
- iv) marker gene;
- v) dissemination of trait to other organisms;
- vi) effects of the abiotic environment—land, wafer, air;
- vii) effects on the biotic environment—wild and domestic animals, insects, fish, birds etc.

4. Extensive discussion focused on the questions:

- when in the process and how to include considerations of potential social and economic implications of biotechnological products; and
- whether the public should be considered a recipient needing information or be an active partner in the decision-making process.

A number of participants argued for more active public involvement in government and in the agribusiness decision-making process with respect to food safety questions. According to these participants, the public, as well as the scientific community, offers valuable insights to government and agribusiness, and the exchange of information between the public and these groups should increase and improve. Additionally, it was argued that risk perception is related to information exchange. An advance public dialog can change perceptions about potential products and provide industry with important information about consumer attitudes.

Debate followed, but the workshop as a whole stopped short of endorsing these points. Participants regarded their principal mandate to be the consideration of the technical basis of food safety and associated regulatory policy. However, the group fully recognized the existence of other dimensions such as social and economic factors in the public perception of safety and refers the reader to the report of the Improving Communication About Biotechnology to cover this area in more depth.

All participants agreed to a more general recommendation that opportunities for involving the public in dialogue on food safety issues should be encouraged.

The adequacy of the Federal Register as a vehicle of public notification was questioned. Several participants suggested there needed to be public forums where concerns and divergent views could be aired before a safety decision is made, while recognizing that not every food or food ingredient could have its own “hearing”.

5. There was consensus that post-approval labeling which would allow consumers to make informed decisions needed more thorough discussion than these workshop sessions allowed.

While the current standards and regulations are sufficient to insure a safe food supply, these regulations are scattered among several federal agencies and there is enormous overlap. The next two recommendations followed from further discussions on the issue of regulatory and assessment methodology harmonization between different agencies, both nationally and internationally. There was surprising agreement.

6. Increase coordination and consistency between federal regulatory agencies.

7. Harmonize and coordinate state and federal regulatory processes (understanding that harmonization does not necessarily imply standardization).

The federal government should play a lead role in those discussions. In addition, there should be movement toward international harmonization of safety standards and regulations.

Further, it is critical that the regulatory review of biotechnologically-derived foods and food ingredients be completed in a timely manner. It was noted that, currently, there are inadequate resources (e.g., budget, staff, instrumentation, etc.) in the regulatory system to address food safety concerns in the time necessary for delivery of products into the market.

## **Appendix**

### **Safety Considerations**

Are there unique safety considerations for biotechnologically-derived products (e.g., transgenic plants, animals and microorganisms)? (If yes, may need new safety paradigm/protocols; if no, do not need a new process, just use the existing one).

Containment for fermentation microorganisms—traditional or different?

Effect of biotechnology on the traditional food safety and delivery system.

Should there be a pre-market review of human food and/or feed products—traditional and bio-engineered?

Avoiding or initiating a total evaluation system for food safety.

Requirements for testing protein toxins (e.g., BT)

Secondary effects of genetic engineering; of the process itself.

Elimination of natural warning systems—how to make safety judgements.

Assessing and identifying safety differences for special populations (especially infants).

### **Regulation and Decision-Making**

Use of biotechnology as a leverage to revise the regulatory system.

Overview of regulatory issues—identify and involve all players.

Regulatory decision tree.

International harmonization and acceptance & compliance methodologies.

State and local regulations re: federal regulation—harmonization.

Balance the cost of regulation vs. the value of the product (cost includes private and social costs).

Is the gene product the only regulated article or should it be something else?

Laws keeping pace with science.

What agencies are regulating; and EPA's role in regulating pesticides produced in plants.

### **Data and Research**

What and how much data are required to support safety decisions and what are the time frames?

Who is doing the research and how is it funded?

Characterization of novel proteins.

Identification and purity of genetically modified materials.

Horizontal transfer of genes.

Need food chemistry and food safety methodologies for traditional and new foods.

Improve database for naturally-occurring toxicants.

Animal feeding studies with whole foods.

Methodology for moving from whole foods to whole diets.

### **Consumer Consideration**

Risk perception.

Identification of the societal and economic factors that impact consumer decision-making regarding the safety of biotechnology.

What sorts and sources of information have credibility with consumer?

Development of food safety information (with appropriate educational strategies) for consumers.

Consumer decision tree.

### **Environmental Consideration**

Defining areas of uncertainty for long term usage (ecosystem wide).

Including environmental and worker safety in food safety decisions.

Use of transgenic pest-resistant crops.

Use of products of biotechnology to reduce the total risk in the ecosystem.

### **Product Issues**

Product identification and segregation issues.

Labeling of genetically-modified foods.

How to open the marketplace for products of biotechnology.

## Improving Communication on Biotechnology

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This workshop met to consider issues related to improving communication and transfer of technical information. The 27 workshop participants began by generating a long list of issues, later clustered into three themes:

1. General and philosophical issues.
2. Communicative and educational strategies.
3. Significant parties.

Three subgroups of workshop participants met to focus on these themes. "Research and evaluation," initially identified as another theme, was addressed by all three subgroups.

Following deliberation by the subgroups, the entire group reconvened to prepare summary remarks to the Meeting. Nine specific recommendations are listed on the following pages. As important as these recommendations, however, is some commentary on how the group redefined its charge in order to promote productive discussion.

### Rethinking Our Task

The original title of this workshop was, "Improving Communication and Transfer of Technical Information." Early in our deliberations, we noted two tensions that were aggravated by this title. First, "communication" and "transfer of technical information" mean different things to different people. Furthermore, placing the terms together suggests that the key to improving communication about biotechnology is simply to facilitate the transfer of technical information among interested parties.

A second problem with the title of our workshop was that the word "transfer" struck some participants as

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disconcertingly unidirectional. Although we noted that “technology transfer” carries other specific meanings in some linguistic communities—specifically in discussing exchanges of data between universities and industries—our conversations dealt with a broad conception of communication. Hence, we chose to discard the expression, “transfer of technical information,” and retitle our workshop, “Improving Communication”.

This semantic streamlining reflects two important conclusions about communication and agricultural biotechnology. First, in talking about technology and food, we must acknowledge the legitimacy of a broad set of values. Concerns about the use of biotechnology in food production are unlikely to be resolved if we discount all but the most “scientific” perspectives. Although scientific research will have a critical role in guiding public policy about biotechnology, other perspectives should be and will be considered. The democratic process is poorly served if we view public policy discussion as a conflict between polemical extremes, such as “scientific fact” versus “emotion”. To communicate productively about biotechnology, we must sensitize ourselves to the many legitimate ways through which humans make sense of their world.

Also critical to promoting communication is that we must distinguish between discussion and monologue. We recommend that efforts should be directed at promoting conversation with more than one voice. Clearly, one part of our communicative challenge is to provide people with accurate information about new technologies and their scientific merits and drawbacks. However, it is unlikely that fruitful discussion will occur among the stakeholders in biotechnology if we fail to recognize that constraining policy discussion to scientific evidence effectively disenfranchises most Americans.

Although the participants in our workshop held many different opinions about the wisdom of promoting agricultural biotechnology, we left with strong consensus on the next steps to take. Discussion about biotechnology is clearly desirable, and should take place in settings where a broad set of perspectives can be aired, considered, and used to guide reasoned human action.

## Recommendations

1. Work toward a national strategy for biotechnology. Although we acknowledge the legitimate involvement of smaller communities in the policy-making process, both the stakes and the costs are very high in the area of agricultural biotechnology. At this time, many states lack the resources to adequately consider the issues raised in this meeting.

To most workshop participants, it appears that the regulatory mechanisms currently governing food safety, which are concentrated at the federal level, serve the public interest and help to ensure safety and quality of food. This is true in part because human and technical expertise is concentrated in a small number of agencies, and in part because manufacturers can familiarize themselves with a comprehensible body of regulations.

Missing at the federal level is a forum for policy consideration and development in the area of agricultural biotechnology. Such a forum would be a useful resource to lawmakers, regulatory agencies, and other groups. We recommend that such a forum be established, and constituted so as to be broadly representative of the stakeholders in agricultural biotechnology, some of whom we identify at the end of our report.

Participants in such a forum may eventually conclude that the best national strategy is to leave many decisions about biotechnology in the hands of state government. Alternatively, participants may argue that agenda setting and legislation should be concentrated at the federal level. We offer no prejudgments, except to note that alternative scenarios may have diverse economic and social outcomes. Food safety and nutritional quality are not the only factors that should be considered in the development of a national strategy.

2. Promote discussion about agricultural biotechnology at many levels.

Concurrent with the development of a national strategy, we recommend that forums for information exchange and discussion be established at the state and local levels. A national forum, although important, will not be directly accessible to most Americans.

3. Encourage the development of credible clearinghouses for information about agricultural biotechnology. Several workshop participants noted that it is unclear where the media or the general public can go for information about agricultural biotechnology, particularly when there are concerns about public health.

We recommend that regional clearinghouses for such information be established, but our group lacked the time and expertise to develop a specific proposal concerning the organization of such clearinghouses. Among the options discussed were university-based hotlines, links with Cooperative Extension, or ties to other existing organizations like the Scientists' Institute for Public Information. Minimally, a regional clearinghouse should be able to refer callers to people who can provide expertise on a range of issues related to agricultural biotechnology. The recent Alar incident, although not biotechnology related, points out how volatile public health sentiment can be about food issues and underscores the importance of taking proactive measures to responsibly handle inquiries.

4 Encourage communication between the media and researchers doing scientific research in the area of agricultural biotechnology. We note that many scientists lack skills or interest in dealing with media representatives. Coupled with the fact that few reporters have expertise in agriculture-related biotechnology, the potential for miscommunication is high.

We recommend that steps be taken to train scientists to responsibly handle media inquiries, and, reciprocally, to provide opportunities for journalists to increase their knowledge about agricultural biotechnology. These two activities might sensibly take place together. Productive communication is facilitated when participants in discourse know each other.

The extension units of Land-Grant universities, which already play an important role in communication related to technical research, should be encouraged to further address issues related to biotechnology.

5. Strengthen all citizens' knowledge about the diverse issues related to biotechnological innovation. Productive discussion about agricultural biotechnology may require significant educational efforts targeted at a number of different groups. Several recent reports have documented the scientific illiteracy of Americans; without question, this impedes public participation in policy discussion about biotechnology. Our group recommends strengthening the teaching of basic bioscience at all levels, the integration of biotechnology into science curricula, and continuing education for teachers in areas related to biotechnology.

Less obvious than the illiteracy of the general public, but potentially as detrimental to effective communication, are other forms of ignorance. Applied biology, for example, cannot be discussed without reference to social, economic, and legal issues. Even among scientists, a toxicologist and an ecologist may use the same words in very different ways; rely upon different standards of evidence, and consequently have difficulty communicating with each other. Productive discussion is not simply a matter of giving people a chance to talk; it requires providing all speakers with a corpus of shared understanding about the topics being discussed.

6. Acknowledge the importance of effective public relations efforts, but avoid substituting public relations for other communications activities. Public relations can be a powerful tool for the diverse stakeholders in the arena of agricultural biotechnology. When a group wishes to promote an attitude, a product, or a position, public relations may be indispensable.

We recommend that stakeholders who use PR as a tool for shaping public opinion continually scrutinize the ethics of their efforts. If stakeholders work hard to know their audiences, acknowledge both the strengths and weak-

nesses of their positions, and avoid misleading or inaccurate statements, the possibility of other forms of productive discourse in other settings is enhanced. Public relations should be used as a credibility enhancing tool.

Public relations efforts alone are unlikely to resolve conflicting positions between different groups of people, because the goal of PR is often to promote a position, not to negotiate resolutions to complex problems.

7. Promote care and consistency in terminology. During this meeting, we noted that biotechnology-related terminology was used inconsistently and could be very confusing, particularly to non-scientists. Given the different groups attending, this inconsistency was not surprising, but it did make communication unnecessarily difficult. A brief but readable glossary of terms would be a useful companion for future meetings, and might also be useful for school teachers, the media, and others.

8. Encourage research on communication about agriculture-related biotechnology. We recommend that multidisciplinary communications research be conducted to help frame and answer questions like the following: What information is needed by participants in discourse about biotechnology? Where do people get information about biotechnology, and how do they use that information to form opinions? How do public perceptions about technology and food influence personal decision making (e.g., food preferences)?

9. Identify other communications needs. We suspect that we have failed to identify a number of other critical needs in the area of communication about agricultural biotechnology, and recommend that assistance be sought from communications professionals to further develop an agenda in this important area.

In conclusion, we offer a list, by no means exhaustive, of some of the groups that have important interests in the development of agricultural biotechnology. Representatives from these groups should be included in a broad scope of communicative activities.

#### Stakeholders

Advocacy groups	Farmers
Consultants	Government officials (elected & appointed)
Consumers	Media
Cooperative Extension	Processors
Distributors	Public Health Professionals
Environmental organizations	Regulators
Exporters	Retailers
Veterinary Health Professionals	Suppliers
Teachers	Trade Associations
Scientists (academic, government and industry)	



## Part Three

## Plenary Addresses

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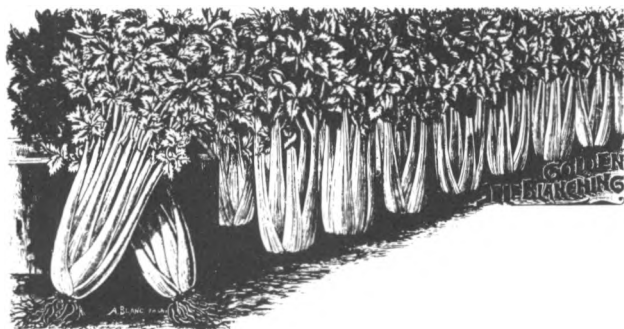
64 Ian C. Munro and Richard L. Hall

Food Safety and Quality: Assessing The  
Impact of Biotechnology

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Food Safety and Quality for the Consumer:  
Policies and Communication

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## **Food Safety and Quality: Assessing the Impact of Biotechnology**

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Reay Tannahill (1973), in her fascinating book *Food in History*, points out that the safety and quality of foods has been a concern of humankind since primitive times. Concerns over food safety and quality magnified substantially along with the development of the food trade, due to the widespread practice of food adulteration employed by earlier food purveyors. It is interesting to note historically that the legislation these practices prompted form the basis for the development of modern food control legislation. But concerns over food safety today extend beyond the question of adulteration which, as we all know, is infrequently practiced by today's food merchants. In terms of their scientific importance, microbiological safety of foods is the predominant concern, followed by nutritional factors, natural toxicants, industrial pollutants, and finally, pesticides and food additives. The emerging science of biotechnology and the impact it will have on food safety and quality is added to these traditional areas of food safety concern.

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To grasp the potential food safety and regulatory issues that might occur pursuant to the introduction of biotechnology into the food and agriculture industry, it is necessary to understand the nature of the issues being dealt with. An industry survey conducted in 1988 by the Food and Drug Administration (FDA, 1988) indicated that about 40 percent of the research and development in food biotechnology was focused on improved agricultural products, 43 percent was targeted at the food processing industry and the balance, approximately 20 percent, was targeted in the area of food safety diagnostics and related applications. The

**The important point here is not the quantitative distribution of resources, but the fact that biotechnology holds great promise for application in essentially all sectors of the agricultural and food processing industry.**

quantitative distribution of resources, but the fact that biotechnology holds great promise for application in essentially all sectors of the agricultural and food processing industry.

Given this breadth of application, what will the major scientific issues associated with the application of biotechnology to the food system be? Certainly the principal concern is one of food safety. A second concern relates to the possible impact biotechnology will have on the nutrient composition of the food supply. From a government perspective, the regulatory issues that will undoubtedly be associated with biotechnology cannot be overlooked. These range from if and how biotechnology food products should be regulated, i.e., "Will specific product approvals be required?", to the whole question of regulatory compliance procedures, including analytical requirements, labeling etc. The impact biotechnology will have on food safety has been evaluated by the International Food Biotechnology

**A key premise of the law, however, is that safety standards and regulatory procedures should be tailored to the nature of the food substance in question and the potential safety questions it may pose.**

potentially harmful to health. A key premise of the law is that safety standards and regulatory procedures should be tailored to the nature of the food substance in question and the potential safety questions it may pose.

Whole foods are not required to undergo any pre-market review or approval by FDA. Under the law, however, any person who introduces food into commerce is responsible for assuring that it complies with all require-

research and development programs in agriculture were evenly divided between livestock biotechnology, the bioengineering of pest resistance into food crops and the development of improved cultivars. In the food processing industry, two-thirds of the activity was focused on new or improved food ingredients while the balance was targeted on food processing techniques such as enzyme technology and improved final products. The important point here is not the

Council (IFBC, 1990) and some of these remarks are based on the recently completed IFBC report.

It is important to consider the legal framework in which we have to operate in any consideration of the effect of biotechnology on food safety. The overriding objective of current food safety laws is, of course, to assure that consumers are not harmed by the foods they eat. To achieve this objective, the law provides an array of safety standards and enforcement tools which the FDA can use to control foods that are po-

ments of the Food, Drug and Cosmetic Act, including the requirement that it meet the applicable safety standards. The FDA has enforcement powers under the statute that permit it to seize adulterated food, seek a court order preventing its further distribution, and criminally prosecute firms and individuals responsible for its distribution.

The law also recognizes that the food supply contains many naturally-occurring substances that, when consumed alone in large amounts, are toxic, but that are not harmful when consumed as inherent constituents of food. The FDA is empowered to act against such substances if it finds that they render the food "ordinarily injurious" to health.

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Substances added intentionally to accomplish a function in food are subject to yet another safety standard, and may be required to undergo pre-market review and approval by FDA. Even here, however, the intent is to foster innovation in food technology, as well as assure safety. These goals are achieved by adopting a protective but realistic safety standard and by not requiring pre-market approval when safety assurance is not required, for example, when the food substance is "generally recognized as safe" (GRAS). As FDA has interpreted and applied the law over the years, formal pre-market approval has generally been reserved for new chemicals and new uses of chemicals that are not GRAS. The FDA has also developed special procedures and practices for the regulation of GRAS substances.

Clearly, the extent of regulatory concern, as well as safety and nutritional components, will vary depending upon the food product or ingredient of biotechnology being considered. To deal with the easy problems first, a regulatory structure already exists to ensure the safety of ingredients such as food additives and GRAS substances. It is fairly clear that new ingredients and even old ingredients produced through biotechnology will be required to meet present regulatory requirements. This covers the bulk of enzymes, microorganisms, food additives such as thickening agents and preservatives as well as GRAS food ingredients such as specific sources of dietary fiber, modified carbohydrates, etc. Collectively, this represents a vast array of substances used by the food processing industry. Except for specific examples, there is really nothing new about these groups of substances. Humans have used microorganisms to "process" foods for centuries, albeit it is only recently that controlled fermentations have been commonplace. Likewise, food additives and other ingredients have enjoyed widespread legitimate use and are now well integrated into the technology of the food processor. The existing regulatory practices will apply to all such products. That does not mean that each new product will require for-

**To comment on the safety issues associated with biotechnology in the food processing industry, it can be safely stated that existing procedures for safety evaluation and regulatory control will effectively eliminate any potential risks that may be perceived to exist.**

mal review by FDA. In many cases, new products will be considered GRAS substances. In a great many other cases, biotechnology is simply a convenient, cost-efficient way to produce existing, already approved food ingredients. To comment on the safety issues associated with biotechnology in the food processing industry, it can be safely stated that existing procedures for safety evaluation and regulatory control will effectively eliminate any potential risks that may be perceived to exist.

The primary issue in food biotechnology relates to its application in agriculture. The real or perceived issues associated with bovine somatotropin are now familiar, along with other emerging problems associated with the genetic manipulation of food-producing animals. Less well recognized, and probably less well understood, are the issues that relate to the application of biotechnology in the plant kingdom. Again, the regulatory and food safety issues differ depending on the application and the end product in question. Two general categories of application can be envisioned. One of these relates to the use of biotechnology to produce herbicide, insect, drought and other forms of plant resistance by engineering foreign genetic material into the plant, while a second category relates more to altering the traditional characteristics of existing cultivars by the insertion of genetic material derived from traditional food sources. These latter changes might include alterations in composition; for example, improved nutritional quality or improved processing characteristics, and increased yield and marketability. In future years the development of new varieties of cultivars, at least new to our palate, might be anticipated.

A record of regulatory experience existing in plants does not yet exist in the safety evaluation of plants or genetic variants of existing plants. Yet a great deal of human experience is available—in fact, many generations of experience in the area of traditional plant breeding techniques. The key to dealing with the problem of biotechnology as applied to plants lies in large part, in the historical experience and the safety record of human use on past practices which exists but is not well documented. The experience of that record provides an important foundation for the safety evaluation of genetically-modified plants.

Primitive humans soon learned which plants were poisonous and should not be eaten and which were not. Yet even today, several poisonous plants are consumed of necessity and are stored, processed or prepared in

such a way as to alter or eliminate their toxicity. A typical example is the root plant cassava which, once properly processed, provides a wholly suitable and nutritious basic food staple for large segments of the world's population. Many other such examples exist, including soybeans, lima beans and even potatoes. Prudent and judicious selection of foods derived from a broad selection of plant fauna available to early humans provided the genetic stock for the plant foods eaten today.

The introduction of plant breeding brought with it not only changes in genetic elements, but vast improvements in the food supply. The genetic lineage of modern cultivars is lost in antiquity, but a perspective on the genetic variations people have historically been exposed to provides an example of the genetic diversity inherent in the present food supply. One of the world's staple foods—maize—probably originated from the wild grass teosinte commonly found in remote areas of Mexico and Central America. Selection and cultivation changed teosinte into Indian corn and finally into modern maize. Unquestionably, humans have been exposed to a wide array of genetic variants of today's maize without apparent adverse health effects over time. The extent of change with time of the genetic diversity in the food supply becomes evident when the differences between cultivated plants and their wild relatives is considered. Cultivated plants usually have one or more of the following traits that are uncommon in their

**The extent of compositional variation inherent in the foods traditionally eaten is another factor to consider in assessing the safety of genetically-modified foods.**

wild relatives: lessened ability to disseminate seed, reduced concentrations of bitter or toxic principles, loss of delayed germination attribute, reduced life span, higher harvest index or altered color and fruit size. This illustrates the point that we and our ancestors have been exposed to wide diversity of genetic material. This becomes important in assessing the impact of biotechnology on food safety.

The extent of compositional variation inherent in the foods traditionally eaten is another factor to consider in assessing the safety of genetically-modified foods. Some of this variation is due to genetic differences, while some is due to environmental influences. Among the macronutrients present in commercial vegetables, intraspecies variations in protein, fat and carbohydrate content range from 1.5-2.5 fold. Similar variations are present in common commercial fruit varieties. Among essential trace elements within species, variations in composition of up to 10 fold are not uncommon. The intraspecies content of some trace elements such as sele-

nium may vary up to 18 fold while vitamin content varies up to approximately 4 fold. While not immediately apparent, these are very wide variations in composition. An example illustrates: if a variety of carrots that contains the higher of the range of vitamin A traditionally present is consumed, all daily vitamin A needs from that source would essentially be met. But if a variety low in vitamin A is consumed, only 25 percent of the daily requirement would be met. This highlights the importance of understanding the impact of biotechnology on the nutrient composition of foods.

A third, and probably the most important factor to consider in determining the consequences of genetic manipulation of plants, is the affect it has on the concentration of naturally-occurring toxic factors. This is a principal concern of regulatory agencies, even while recognizing that traditional plant breeding practices have been used to advantage to reduce levels of toxic constituents. In the early 1970s, FDA cited six incidents which raised questions of safety regarding traditional plant breeding and which brought these practices under the purview of GRAS regulations. These included:

- a 60 percent increase in solanine content of potatoes grown from seed tubers treated with 1,000 rads of gamma radiation to break dormancy;
- the development of a high solids potato cultivar with high solanine content;
- the hypothesis that potatoes resistant to late blight developed additional chemicals that are teratogenic;
- the production of the toxic chemical ipomeamarone by sweet potatoes under certain environmental conditions;
- the development of cultivars of food plants resistant to insect attack;
- unexpected changes in plant composition due to other varietal changes (the example given was reduced vitamin C in tomatoes due to mechanical harvesting).

The FDA indicated that an increase in toxicants of 10 percent or more when compared to the parent containing the least toxicant, or a decrease in a principal nutrient of 20 percent or more, would require that appropriate analytical data be supplied to FDA in a GRAS affirmation petition.

Despite plant breeder's concern over FDA regulation the vast majority of new plant varieties have not been formally reviewed under GRAS regulations and have not required pre-market approval from the FDA. Nonetheless, we must be vigilant to the possibility that biotechnology may introduce new toxic factors into plants or alter the levels of existing toxicants.

There are now over 200 naturally-occurring toxic factors in food that have some potential for causing toxic effects in humans, although only 21 have been firmly documented as causing human harm. These include both toxic factors in food plants and in animal feeds and forage where the toxicant is passed on to human food such as milk. These are important for the plant breeder to consider because:

- Selection and traditional breeding practices have been among the most successful methods used to reduce concentrations of natural toxicants to levels that present no significant hazard;
- Natural toxicants will clearly be the principal point of concern in evaluating the safety of foods produced by genetic modification of sources in which these toxicants can occur;
- It should certainly be the intent of any genetic modification to reduce, or at least maintain the level of any constituent that even approaches being a significant hazard;
- Natural toxicants are an important, and, within professional circles, a well-recognized source of risk in food.

As with nutrients, genetic variations may markedly alter the toxicant content of foods. For example, the solanine content of white table potatoes may vary from 2 to a high of 20 mg/100 g, a ten-fold variation. The higher level could represent 20 percent of the toxic dose of solanine to humans. In fact, during the 1970s, the U.S. Department of Agriculture (USDA) developed a potato variety (Lenape) with unusually high solids content and, therefore, desirable processing characteristics. This variety also derived late blight resistance from a wild ancestor, *Solanum demissum*. In the course of routine monitoring of incoming potatoes for glycoalkaloid (solanine) content, a food company found solanine levels several times higher than normal in the Lenape variety. The company called the problem to the attention of USDA and FDA and the variety was quickly withdrawn. Similarly, low cyanogen varieties of cassava yield 20 - 40 mg/kg of hydrogen cyanide while other varieties may yield 20 times that amount—enough to poison a person who is not aware of the proper processing procedures.

The examples quoted are clearly well known, but the potential for genetic modification to alter the levels of less well known toxicants must never be overlooked. As recently as 1981, Rymal et al (1984) reported that as the result of quality control testing, a large commercial pack of tomato sauce containing squash was kept out of commerce because the squash was found to be extremely bitter. Samples of the fruit of this cultivar were found to contain unusually high levels of the extremely toxic substance



Cucurbitacin E. This episode, as well as others where people were actually poisoned from home garden crops in Alabama and Australia, apparently resulted from a "wide cross" contamination of the cultivated seed from a wild relative.

### **Criteria for Assessing Safety and Acceptability**

This provides the background to attempt to elaborate on the criteria that are important in assessing the safety and acceptability of genetically-modified food crops. If the process of genetic modification is intended to introduce new genetic elements that result in a wholly new expression product, for example, a resistance factor such as a pesticide derived through enzymatic means, then clearly we should in theory, identify and characterize the substance, its range of levels of occurrence and conduct a safety evaluation on it as a discrete entity if possible. If it is not possible to isolate the substance, it may be necessary to evaluate the safety of the whole food.

If the genetic change is intended to enhance the nutritional quality of a food, then documentation supporting the achieved objective would be required. If the genetic change was intended to enhance processing characteristics, yield or marketability, this would likewise need to be demonstrated. In all cases, a critical feature of the safety evaluation would consist of characterizing the nature of the introduced genetic material, particularly if it is not from a traditional food source. The following should be known about the inserted genetic material:

- the physical and functional limits of the coding region, and size and structure;
- the physical extent of the signal DNA regions;
- the functional properties of signals such as promoters where the sequence, relative strength and start of transcription are known from published literature or direct determinations.
- after the genetic material is introduced and an individual genetically-modified plant has been selected, the following additional information may be obtained: quantitative data on the levels and consistency of the expression products from the introduced gene.
- copy number of the introduced gene and vector sequences.
- documentation concerning the concentration of significant nutrients in the product. Significant nutrients are defined as those that contribute in a major way to achieving recommended daily intakes. Other nutrients, though important, would not be critical to gaining acceptance of the product.

Documenting the levels of any known naturally-occurring toxic factors inherent in the plant species or its close relatives. This would involve analytical determinations of the precise levels of those naturally-occurring toxic factors in the food on which attention should focus.

If deemed necessary, documenting that genetic manipulation has not altered the physical and elemental composition of the food in such a way as to impinge on the microbiological safety of the food when processed in accordance with usual practices.

In practice, it is important to revise these criteria in light of the principle that the standard of safety for biotechnologically-produced foods should be no more or no less stringent than that required for food produced through conventional breeding techniques. What can be concluded about the impact of biotechnology on food safety? It can be stated safely that food ingredients and additives produced through biotechnology will not be a new issue to the science of food safety because of the well established safety evaluation practices that exist for these classes of substances.

With respect to whole foods such as genetically-modified plants, the extent of safety evaluation will need to be geared to the nature of the induced genetic change. Given the specificity of modern techniques in molecular biology, as applied to biotechnology, changes in genetic composition hopefully could be characterized with greater ease and more precision than in the past. The genetic alterations induced through genetic engineering probably would not be as extensive as those induced through tradi-

**The science of food safety has the tools and the know-how to provide a rigorous safety evaluation of new products. If good science leads, fair regulation will surely follow.**

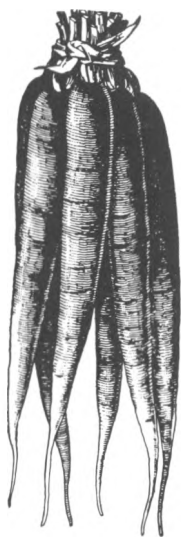
tional breeding practices, especially wide crosses. This tends to limit the extent of compositional change that might occur. The degree of government regulatory oversight required will depend on the degree of technical excellence the industry demonstrates. The reward for adequately characterizing introduced genetic material, and providing other data referred to will be reduced time to approval in cases where pre-market approval is required. The penalty for failing to do so will be increased regulatory scrutiny consisting

of repeated requests for more data, more complete explanations, and, worst of all, requests to test the new product in extensive animal feeding trials. This is to be avoided in the name of good science.

The science of food safety has the tools and the know-how to provide a rigorous safety evaluation of new products. If good science leads, fair regulation will surely follow.

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## Food Safety and Quality For The Consumer: Policies and Communication

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Good morning. As a student thirty years ago, 8 a.m. classes were the bane of my existence. Any professor who hoped to keep me awake had to have the oral equivalent of the 1812 Overture. It is with that memory and concern that I would like to begin this morning with a few quotes:

Hydrochloric acid is the same acid contained in the human stomach. So said a spokesman for the Society of the Plastics Industry, on why plastic, which gives off hydrochloric acid when it is burned, could not be an environmental irritant.

Most of the chemicals are not a problem as far as adverse effects...The stuff you smell is not necessarily anything to worry about. The reassuring response of the Health Commissioner of Niagara County, New York, to the residents of the Love Canal area.

There was nothing there that was catastrophic or unplanned for. The calming response of the vice president for power generation of Metropolitan Edison, owner of Three Mile Island nuclear power plant, 1979.

A nuclear power plant is infinitely safer than eating, because 300 people choke to death on food every year. Dixy Lee Ray, Governor of Washington, 1977.

Opponents of peacetime applications of 2, 4, 5—T have repeatedly launched false, malicious attacks on the safety of the product. Dow Chemical Company fact sheet after an investigation concluded the manufacture of Agent Orange creates dioxin.

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DDT, the most effective pesticide, was outlawed on the theoretical grounds that it might someday, under some circumstances, harm someone. Ronald Reagan, 1978-Quoted in Arbeiter, Jean, No Matter How You Slice It, It's Still Baloney (Quill. New York, 1984.)

We must help the public understand that a genetically engineered tomato is still a tomato...and that this research is being conducted by responsible scientists operating under a strict and credible system of safety guidelines. Assistant Secretary of Agriculture Charles Hess, 1990 Remarks Prepared for Delivery to Conference on New Food and New Food Chemicals: Safety and Regulatory Considerations, at the National Academy of Sciences, May 1, 1990.

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Consumers must understand they do not live in a risk-free society and that some risk is necessary for all the benefits that today's technology brings. Luther McKinney, Senior Vice President, Quaker Oats Company "Fields of Fear," Choices, American Agricultural Association. First Quarter, 1990.

One of the hardest things in the world is to convey meaning accurately from one mind to another. Lewis Carroll

What we have here is a failure to communicate. Prison Warden to the still defiant prisoner, Luke, after he has put Luke in chains, compelled him to dig a hole and then knocked him into it...the motion picture Cool Hand Luke.

As we approach the twenty-first century, the further development of biotechnology holds the potential for enormous benefits to society. Advances in genetic engineering can improve health and control pollution. Biotechnology can bring us more efficient agriculture by enhancing productivity of the land, reducing quantities of water and energy needed to raise a particular crop, and expanding the geographical range of many crops. Biotechnology can address important consumer concerns about food. It can: improve food safety by reducing the need to use insecticides and herbicides; improve nutritional value of food by helping to produce leaner meat; enhance the flavor and the processing capability of food; identify and reduce the microbial contamination that brings food-borne illness and death to thousands of Americans each year.

**Given these virtually indisputable benefits, one wonders why the crowds aren't cheering in the streets.**

Given these virtually indisputable benefits, one wonders why the crowds aren't cheering in the streets.

Why instead, are people concerned—even frightened—about the potential impact of biotechnology on our food supply and our lives? Why does Jeremy Rifkin have an audience? Why do people buy Jack Doyle's book? It cannot be dismissed as just another example of America's love of gothic tales and horror stories. What steps can the biotechnology industry and the government take to ensure that the American people are sufficiently comfortable with the purposes, benefits and application of biotechnology that they will not unduly restrict its development?

### **Reasons for Concern**

76 There are a number of reasons that Americans are concerned about the impact of biotechnology. First, all understand that biotechnology involves certain potential risks. There may be health risks arising from the consumption of plants that contain bacteria designed to kill pests. Genetically-engineered microorganisms may be capable of attacking other microorganisms, plants and animals in unexpected ways. Species under attack by genetically-engineered organisms may develop resistance to the toxins. There is a threat of ecological damage, as well. The development of herbicide-resistant plants may encourage the use of more, not less, of toxic materials which may harm wildlife. Biotechnology will surely bring socioeconomic change that will harm some farmers and suppliers, while benefiting others. The debate about bovine somatotropin (BST) in Wisconsin continues to be driven by these concerns.

Second, the social and political context in which the biotechnology revolution is occurring is not conducive to an enthusiastic and unquestioning acceptance of any new scientific or technological breakthrough. In the 1950s virtually all Americans believed that there was "Better Living Through Chemistry." Today, we are not so sure about it. Americans have lived through forty years of "Don't Worry, Be Happy" philosophy about new technologies, many of which were put on the market without any examination of the potentially negative unintended consequences of their use. All were told of the promises and none of the problems with DDT, aerosol sprays, and nuclear power. When problems arose with some of the products, both government and industry were less than honest in reporting them. Today, Americans are more skeptical. Instead of accepting scientific developments as a cornucopia, many see just another opportunity for Murphy's Law to rule.

The public's view of new science and technology is unquestionably colored by this history, and their view of biotechnology will also be influenced

by government's and industry's attempts to "communicate" the virtues of these new developments.

### **"Communication" Problem**

The proponents of biotechnology have approached these public concerns as a "communication" problem. Considering the enthusiasm for this exciting new field among those involved in it, that is not surprising. Some enthusiasts in government and the food industry believe the best approach to resolving fears about biotechnology specifically or the safety of the food supply generally is to "educate" the public.

**There is an assumption that, if the public can just be made to understand, it will open its arms and receive biotechnology as an unmitigated blessing.**

In this case, "educate" should be read as "reassure." They believe public concerns are based on misperceptions and unjustifiable fears. There is an assumption that, if the public can just be made to understand, it will open its arms and receive biotechnology as an unmitigated blessing.

Occasionally, efforts to "communicate" express less than a high regard for the intelligence of critics. In

fact, they sometimes take on the tone of the old "Saturday Night Live" satire of the Jack Kilpatrick—Shana Alexander face-offs on television news. You may remember the "Saturday Night Live" version would open with Jane Curtin giving her statement on an issue of the day. Dan Akroyd would then begin his rebuttal with, "Jane, you ignorant slut." That tone creeps into food industry and even government responses to consumer concerns about food safety in general. People concerned about the long-term impact of pesticide residues or herbicide-resistant corn are viewed as a flock of Chicken Littles, clucking inanely that the sky is falling. Industry and government officials seem to assume that if they can just get the silly chickens to understand what a great thing this will be, they will snuggle up to it like a warm lightbulb on a cold night in the henhouse. The jarring, condescending quotes at the beginning of this paper are not atypical. Rather, they reflect a common tone in both advocacy and defense of new technologies.

There are two problems with the "communication" as "reassurance" approach. It misunderstands communication. Communication is not Me speak,—You listen...Me teach,—You learn. Me say,—You do. It is a two-way street. It requires that both parties have the opportunity to speak and to listen, to hear and be heard, to act and to respond.

More importantly, there is a problem with assuming that communication will resolve public concerns about biotechnology. Differences over

**Communication is not, Me speak,—you listen...Me teach,—you learn. Me say,—you do. It is a two-way street.**

this issue may represent not a failure to communicate, but a conflict in values. The risks and benefits of biotechnology do not necessarily accrue to the same individuals or groups. Getting the farmer a herbicide-resistant crop does not necessarily get the consumer anything. Economic theory suggests that increased production will generate lower prices, but in the real

marketplace, there are too many steps between farmer and consumer to assume or even hope that the savings will reach the ultimate retail purchaser. Some consumers may prefer to forego both the advantages and the threats of biotechnology. Consumers may feel there is no benefit to them in a technology that promises increased productivity, but does not promise that savings will be passed through to the purchaser. Small farmers may fear that new products will put them at a competitive disadvantage.

Assistant Secretary of Agriculture Charles Hess noted recently that the debate over BST is about social and economic policy, not about science. He is right. If it were simply about science, effective communication might address the problem. But if it is about social and economic conflicts, a conflict of values and interests, communication alone will not do the job.

Resolving these conflicts requires a mediating institution. In a democratic society, conflicts of values are ultimately resolved by government—by legislators, by regulatory agencies and by courts. In our system, the public must be comfortable that the hard questions about biotechnology are being addressed effectively by the government. And they must believe that government's first priority in this endeavor will be to protect public health.

That is not going to be easy. The biotechnology industry began to develop rapidly about the same time the United States was entering a period of "deregulation." Regulatory activity tends to run in cycles. From the early 1960s to the late 1970s regulation, especially regulation designed to promote health and safety and prohibit invidious discrimination, expanded significantly. In the late 1970s, the public began to view this regulation as partly responsible for the nation's economic difficulty. President Jimmy Carter tried to rein in regulation. Four years later, President Ronald Reagan ran and was elected, in large part, because he promised to get government off the backs of American business and let the economy rebuild itself. Reagan appointed officials who were committed to cutting back on business regulation and on government services. Regulatory agency bud-



gets and staffs were cut and new regulations were reviewed and frequently killed by the Office of Management and Budget.

A substantial erosion of public confidence has grown out of the era of deregulation. We have a tradition of limited government but we expect government to ensure that our planes are safe and reasonably on time, that purchasing a telephone will take less time than buying a house, that air and water and food are reasonably clean and that the money we put in a Savings and Loan will be safe. After a dozen years, "deregulation" is wearing thin.

**A substantial erosion of public confidence has grown out of the era of deregulation.**

Nowhere is this concern with the effects of less government control more evident than in the public concern about the environment and the safety of food and water. The scandals of the EPA during the reign of Anne Gorsuch and Rita Leveille and the attack on environmental laws by Secretary James Watt have undermined public confidence that government agencies are working hard to protect public health and safety and the environment. The results have included a willingness to believe sensationalist attacks and a growing reliance on responsive state regulation, rather than unresponsive federal regulation.

President George Bush and the Congress are moving to try to restore some confidence in the regulatory agencies, trying to increase budgets, hampered by the budget deficit. The Bush regulatory team, like the President, appears to be less ideological and more committed to making government work. However, we will live with the legacy of the 1980s and efforts to generate support for biotechnology must take into account the context of American society today. There is little trust that the federal government will play a vigorous role in protecting the people or the environment. At

the same time, American business, including the biotechnology industry, fear the delay and adversarial nature of the regulatory process and the possibility of 50 or more different sets of state and local regulations,

**Resolving these conflicts requires a mediating institution.**

### **Benefiting From Biotechnology, Safely**

If we want to enjoy the benefits of biotechnology while saving ourselves from unintended negative consequences, we need to take some specific steps.

First, the President of the United States should find an occasion to state simply, plainly and very strongly that the very first concern of the government will be the health and safety of the American people and that the development of biotechnology will be allowed to proceed only as long as it

can be shown to be safe. True conservatism, not libertarianism, is an appropriate approach for the leader of the party of Teddy Roosevelt.

The industry should not fear such a statement. Surely this view is held by everyone involved in the development of biotechnology. This new field may hold great hope for our nation's international competitiveness and for improving products, but no one wants it at the risk of public safety. The President should say that.

Second, the Administration, with support of the ... **activists** **ars** biotechnology industry, should propose changes in regulatory procedures and the law, if necessary, to open regulatory processes to a very high level of public participation and make funds available to support vigorous public participation.

Let me talk a few minutes about "public participation." It is not the same thing as public relations. There are several "publics" that must be addressed. They include: —environmental and consumer activists who follow the progress of new technology and new regulations closely;—state and local public officials;—national and local media and the public at large.

The first three groups will have a major impact on what the last group thinks and how they react. Despite the worst fears of industry and government, activists are going to have a role in regulatory decision making. The sooner they are involved and the better equipped they are to address the scientific and technical issues involved in a decision, the less impact they will have on the timing and perhaps the substance of regulatory decision making.

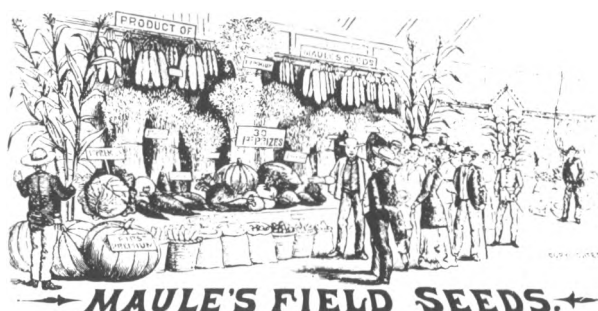
It is not enough to file a notice in the Federal Register to hold a hearing. Nor will it do much good to try to go around those most likely to raise difficult questions. If there are value conflicts to be resolved, knowing what they are early should improve the decision making process. If businesses and government know, in advance, and before they are committed to a course of action, what issues are likely to cause the greatest protest by consumer and environmental activists, alternative courses can be adopted. Relatively small changes early in the process may save substantial amounts of time and money later.

Third, it would be useful to create a quasi- or non- governmental mediating organization to deal with specific issues. There are some interesting examples of groups that have worked over a period of years to ease regulatory issues. The Joint Labor Management Committee of the Food Industry

involves the major retailers and the trade unions that organize them. They meet regularly to try to avoid the most divisive industry wide issues. The Health Effects Institute is a private, non-profit organization funded by government money authorized under the Clean Air Act and the auto industry to set and carry out a research agenda on major auto-related clean air problems. A variation of this group could help set the research agenda for major biotechnology questions. It should involve individual scientists who are known to have a strong environmental bent.

Reducing conflict will not be easy and many fear both delay and the threat to trade secrets that may be involved. Industry leaders also may fear that they will participate in such an activity, only to be attacked by some activist not involved in the process. Any and all of those things may happen, but history indicates that a considered approach to the introduction of new technology provides the greatest opportunity to avoid unintended and unpleasant consequences. Moreover, Congress, regulatory agencies, the media, state and local officials and the public at large are likely to be impressed by any decision which has the endorsement of leaders of both consumer and environmental organizations and biotechnology leaders, and that certainly is possible.

These kinds of changes in the decision-making apparatus can improve "communication," reduce value conflicts, and ultimately improve the public policies governing biotechnology. Perhaps we can write this chapter of American history without creating another set of painful misjudgments.



## Part Four 82 Lectures

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### Our Food Supply: How Safe?

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- 84 **Joseph H. Hotchkiss**  
Food Related Risks:  
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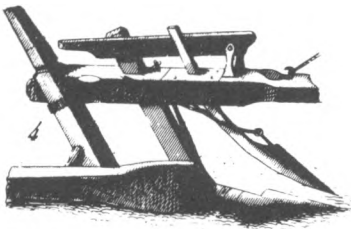
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## **Food Related Risks: A Food Scientist's Perspective**

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### **Safety, Risks and Hazards**

The term "safety", while commonly used when discussing foods, has little scientific meaning. "Safety" implies an absence of harm, just as "honesty" implies a lack of dishonesty. Such terms cannot be quantified in a scientific or general sense and so are not scientifically useful. Scientists think of food safety in terms of hazards and risks. A hazard is the capacity of a thing to cause injury or harm while risk is the statistical probability that harm will result (NRC,1983). The difference between hazard and risk can be understood by using the analogy of traveling to Europe by boat. The hazard is that the boat will sink and you will drown. The risk depends on the type of vessel you are traveling on; if it is the Queen Elizabeth, your risk is low, if it is a wooden row boat, your risk is high. Scientists think of food safety in terms of hazards and risks, usually in a comparative sense. Hazard analysis identifies a food substance which at some level or amount, might cause harm. Risk assessment gives the probability the harm will occur. The magnitude of risk depends on the potency of a toxicant and the dose encountered.

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### **Food-Related Risks**

All foods, regardless of source, have both environmental and human health risks associated with their production, manufacture, and consumption. These risks are generally qualitatively similar whether foods or additives are from traditional sources or derived from biotechnology. Biotechnology has presented few, if any, new Or unknown challenges in food safety. Food related risks resulting from biotechnology differ from traditional risks only in the speed with which they can

**Food related risks resulting from biotechnology differ from traditional risks only in the speed with which they can be introduced into the diet and their potential to quantitatively change American diets.**

be introduced into the diet and their potential to quantitatively change American diets. The major challenge to regulating food safety from biotechnology relates to the numbers of safety decisions which must be made. Regulators of food safety and those developing new foods or additives from biotechnology must insure (and convince the consumer) that non-traditional foods are of equal or lower risk and greater benefit than traditional foods.

The health-related risks associated with foods, regardless of the source of the food, can be divided into six categories:

1. Pathogenic microorganisms Microbiological risks, such as the occurrence of pathogenic bacteria like *Salmonella enteritidis* or *Listeria monocytogenes*, in foods are the most well characterized food-related risks (Ryser and Marth, 1989) and are usually given top priority. Pathogenic foodborne microorganisms are responsible for hundreds of confirmed deaths of United States residents each year (Archer and Kvenberg, 1985). The actual number of deaths is probably well into the thousands per year. Biotechnologically-derived foods must insure that they do not increase these risks by altering foods. For example, genetic alterations of tomatoes which produce desirable cultural or disease-resistance characteristics would increase microbial risks if the acid content were reduced to the point where the pH was greater than 4.6 and microbes could more readily grow.

**Nutritional misuse of** One of the food-related objectives of biotechnology foods may be the most that has not been adequately addressed is the role of common food safety biotechnology in reducing food-borne disease. For example, in the United States, **problem** **In the United States** **amplified here** are naturally occurring compounds

which at relatively low levels can inhibit the production of toxin by *Clostridia botulinum*. If added to foods, either as the chemical, or through inoculation, or biotechnologically, the potential for botulism would be greatly decreased.

2. Nutrition-related disorders The risks resulting from the misuse of foods are nutrition related. With a few exceptions, United States residents do not suffer from a lack of nutrients in the classical nutrition sense, but imbalances are common. Nutritional misuse of foods may be the most common food safety problem in the United States. The over-consumption of fat in the American diet, for example, has been discussed by several health authorities as undesirable and as increasing our risks of chronic disease. Less than optimal intake of some nutrients such as iron by some seg-

ments of the population is a further example of a food-related health risk. Changes in major components (e.g., fat) of the American diet may be possible through biotechnology. These may have both beneficial and negative nutritional impacts.

In addition, nutrition research is advancing our understanding of the relations between diet and chronic disease (U.S. HHS, 1988). Less-than-optimal diets increase the risk of chronic life-threatening disease including heart disease and cancer. As a recent study from the National Research Council (NRC) points out, application of biotechnology shows promise as a way to improve the nutritional attributes of some foods (NRC, 1988).

3. Naturally-Occurring Toxicants. Recent evidence suggests that the occurrence of natural toxicants in the diet may be a larger risk than commonly perceived (Ames et al., 1987). We have learned to avoid acute toxicants but the role of low levels of substances such as aflatoxin (a mycotoxin derived from molds), plants toxins, or the formation of mutagens when foods are cooked is unknown (Sugimura, 1986).

This food-related risk may be the greatest unknown and largest problem for foods derived from biotechnology. There are cases where new varieties of edible plants obtained by traditional plant breeding contain sufficiently increased amounts of a toxin compared to the older variety to cause acute toxicity in humans (Concon, 1988). For chronic toxicants, such as naturally-occurring chemical carcinogens, the problems become more difficult. How should one view a new vegetable variety with both desirable

**As a recent study from the National Research Council points out, application of biotechnology shows promise as a way to improve the nutritional attributes of some foods.**

cultural attributes and an increased level of a compound that will cause tumors in laboratory animals when fed at very high levels? This question is not unlike the debate surrounding the occurrence of low levels of human-made carcinogens such as pesticides, in foods. The speed with which new plant and animal breeds may be derived increases the odds of co-developing naturally occurring toxicants.

4. Adventitious contaminants One of the consequences of modern life is the contamination of the environment by potentially toxic substances. Modern food production and processing can result in the adventitious addition of trace amounts of some of these substances to our foods. Polychlorinated biphenyls (PCBs) are prime examples (Safe, 1987). The occurrence of extremely small amounts of PCBs in food cannot be totally prevented, but most toxicologists would



agree that current levels do not represent a significant hazard. Adventitious additives can also migrate from food contact surfaces such as plastic packaging (Hollifield et al., 1988).

Despite much publicity, we control these risks reasonably well because we usually understand much about these contaminants.

5. Pesticide residues Pesticide residues are a risk but at a much lower level than is commonly perceived. Premarket testing requirements (especially for newer pesticides) and strict monitoring of residue levels has helped ensure that this risk remains low (Gunderson, 1988). Biotechnology can produce plants with greater disease resistance, and hence, a reduced need for pesticides but caution must be exercised. Pest resistance is often a result of phytochemical defenses. Cancer or other toxic risks could be increased when resistance results from increased biosynthesis of naturally occurring toxicants. We may be trading the risk from human-made pesticides of known toxicity for plant-derived pesticides of unknown toxicity. A major food safety problem in viewing biotechnology as an approach to decreased dependence on human-made pesticides will be developing way of comparing risks from human-made pesticides to those of naturally occurring pesticides.

6. Food additives Despite the common perception otherwise, a considerable amount is known about the safety of food additives. Strict toxicological and use testing of each substance used as an intentional food ad-

ditive is required. Labeling of foods containing food additives is also required. In fact, there is indirect evidence that some additives (e.g., BHT) may reduce cancer risks (Doll and Peto, 1981).

Biotechnology may produce a variety of new additives or produce current additives more cheaply. These additives will have to undergo the same rigorous safety testing procedures as current additives.

**A major food safety problem in viewing biotechnology as an approach to decreased dependence on human-made pesticides will be developing way of comparing risks from human-made pesticides to those of naturally occurring pesticides.**

### **Identifying Hazards and Determining Risks**

Much effort has been expended in testing for hazards that may be associated with foods. For microbial contaminants, significant progress has been made in the use of rapid screening methods. These methods are generally based on some fundamental biological or genetic principle; immunoassay, for example. Chemical contaminants can be routinely detected in foods at levels lower than 1 jig per kilogram of food. For many contaminants this equates to a daily intake of less than 10 nanomoles per day per person.

The problem is not in qualitatively or quantitatively identifying food-borne hazards but rather interpreting the risks associated with the hazards, if present. This is the same dilemma that foods derived from biotechnology must face. For chemical hazards, the fledgling science of risk assessment (NRC, 1983) seems the best currently available tool to assess risk, although the methods are not without sincere critics. Risk assessment, in some form, has partially replaced the zero tolerance approach of older risk control laws such as the Delaney Clause. The Delaney Clause sets a zero tolerance for food additives which "are shown to cause cancer in man or animals" (NRC, 1987).

It has been standard practice to essentially set a zero tolerance for some microbiological hazards; if a food contains certain pathogenic bacteria such as *Listeria monocytogenes*, then its associated risk is deemed too high. Unfortunately, this zero tolerance is unworkable and often ignored. Once again the problem is assessing the degree of risk associated with low numbers of a given pathogenic bacteria in foods. Put another way, how many of a specific pathogenic bacteria must be consumed in order to represent a significant risk? This number has not been determined for most pathogens. How new technologies such as packaging might influence microbiological risk is also of current concern.

## Conclusions

The hazards associated with foods in general have been determined. Biotechnology presents few hazards not previously considered and in some cases could substantially reduce risks. Unfortunately, food products derived from biotechnology will face the same dilemma as traditional foods when it comes to determining the magnitude and acceptability of each individual risk.

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## Food Related Risks: A Nutritionist's Perspective\*

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This paper presents a nutritionist's perspective on a number of issues consistently raised when discussing food and biotechnology.

The nutritionist has not always been welcome at the table when the talk was about technology. In fact, any time nutritionists get into a discussion about technical changes in the composition of the food supply our advice has not been particularly helpful, due to the fact that technology must focus on a particular crop or food rather than the whole nutritional picture.

A direct antecedent of this meeting was the interest that was generated in the 1960s, when, at Purdue, Nelson and Mertz (a plant breeder and a biochemist) discovered a particular gene in maize associated with higher lysine content of the corn, called the Opaque two gene—opaque two corn, or high lysine corn. As lysine is the most limiting amino acid in corn protein for the growth of many animals, this was exceptionally exciting. This discovery introduced the possibility of raising pigs by feeding them little more than high lysine corn with minor vitamin and mineral supplements. In addition, preliminary testing in adults and children revealed that diets consisting primarily of Opaque corn retained nitrogen more efficiently. Amidst an exceptional amount of promise and hyperbole, this development was considered as potentially eliminating hunger and malnutrition in the world.

That finding led to the idea that crops could be manipulated to affect nutritional value. This idea caused great excitement and led to plant breeders and nutritionists sitting down together to discuss the available technological options with the goal of improving the

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\*edited from tape of  
presentation

nutritional quality of the food supply. Later work demonstrated that the early promise would not come as quickly as was hoped. Work showed that the yields of some crop varieties incorporating the Opaque gene were low, the milling quality of the grain was changed, and its disease resistance was poor, clearly demonstrating that many other factors needed to be considered alongside nutritional content in order to create a successful crop.

About the same time, United States Agency for International Development (USAID) carried out three major field studies around the world in order to look at the effect of supplemental lysine in populations where either wheat, corn, or rice was the major staple cereal. These grains are a major source of calories in many populations around the world.

For example, a study was done in Morocco supplementing wheat with lysine. In Thailand, a study was done adding lysine to rice, and in Guatemala, lysine was added to corn. These studies were unable to show nutritional benefit from the improved lysine content in any of these populations.

Why did the laboratory control studies show such elaborate and important effects from supplementing grain proteins with lysine, whereas the field studies did not? This was due to several factors: human feeding studies are difficult to carry out, and results difficult to interpret. Human lysine requirements are probably quite low, particularly when compared to rapidly growing rats, pigs, and chickens, and therefore the extrapolation of these animal studies to human populations was probably unwarranted. More importantly, even though the maize, wheat, or rice was the predominant staple, people still eat a variety of foods which complement each other in nutritional quality.

**People eat a variety of foods, even in situations where there is very specific and heavy dependence upon one source of food for calories.**

While the discovery of the Opaque two gene was certainly very important, the effects of any new development must be considered within the context of the entire diet, and not as a single food.

New varieties of "quality protein maize", (as opposed to Opaque two corn) now eliminate many of the problems seen in earlier varieties. Yields are up, and the milling quality and other agronomic characteristics have been improved. Once again these varieties are still associated with much hyperbole and promoted as potentially eliminating many of the world's nutritional problems.

People eat a variety of foods, even in situations where there is very specific and heavy dependence upon one source of food for calories. Thus diet quality is measured by the sum total of everything eaten, and is not generally based on a single crop or product. Cereal promotions based on the concept of one cereal providing all nutrients necessary continually set a nutritionist's teeth on edge.

Following this era of discovery in the 1960s, nutritionists began to collaborate with plant breeders. Nutritionists were asked, "What should targets be in changing the composition of food? What should be done?" Plant breeders were confident that they could select for specific characteristics desired, saying, "Look. You give us some characteristics to select for, and we'll give you those characteristics." However, it is nearly impossible to predict what targets should be set for a particular food in order to improve the nutritional quality of the diet and thus improve the health of the United States or some other part of the world. Again, the problem is that people do not eat nutrients. They eat food, and they do not eat a particular food, they eat a variety of foods. That continues to be the dilemma as nutritionists and technologists interested in a particular crop discuss what we could do to make foods better nutritionally.

In the United States today, concern about human nutrition does not, for the most part, focus on deficiency disease. Within this context, setting targets for given levels of nutrients is not helpful. Increasing the lysine content of corn, the thiamine in cereal grains, or vitamin C in oranges would not improve the health of the American population. However, levels of saturated fat and cholesterol, the consumption of some kinds of carbohydrates, and changes that occur in manufacturing of foods through the addition of sodium and other things of this nature are of prime concern.

As public health problems are examined, the major causes of death are still heart disease, cancer, and conditions associated with them such as stroke, diabetic complications, and the interaction of these conditions with obesity. Increasing evidence points towards modifying these conditions and their progress through diet. Thus diet, as it relates to these conditions, has important public health considerations.

The dietary guidelines for Americans, currently in its third edition, has just been submitted to the Health and Human Services (HSS) Secretary and the Director of the United States Department of Agriculture (USDA), who will publish new guidelines in October. The third edition has not changed significantly from the first and second edition, and it will read something like this:

The first guideline: eat a variety of foods.

A varied diet virtually insures sufficient amounts of the various nutrients required for good health. If you do not get some nutrients from one food, you will get them from others. There is all this complementarity of foods that we have learned about over the years.

**Consuming a variety of foods has important food safety implications.**

In addition, consuming a variety of foods has important food safety implications. Within a varied diet are specific foods which each contribute nutrients and in some cases toxins to the total diet. The variety insures that no one item provides a majority of total nutrition for better or worse. Therefore, consuming a variety of foods makes it less likely that you are going to have food safety problems (e.g., consume excess toxins or pesticides). Variety is always the first on the list. Eat a variety of foods.

The second guideline: maintain healthy weight. There have been some interesting problems in attempting to determine exactly what is a healthy weight, but nevertheless, that is the guideline.

Other guidelines include: Choose a diet low in saturated fats and cholesterol. Choose a diet with plenty of vegetables and grain products. Use sugars in moderation. Use salt and sodium in moderation. If you drink alcoholic beverages, do so in moderation.

A few years ago, because of the above kind of nutritional concerns of the American public, the Division of Nutritional Sciences at Cornell University was asked by the USDA to help set a research agenda for the Agricultural Research Service (ARS) to meet dietary guidelines.

Together with Hub Allaway, who used to direct the Federal Plant Soil & Nutritional Laboratory in Ithaca, three workshops were held. A group of plant scientists, a group of animal scientists and a group of food scientists were brought together (with some mixing of the three groups in the workshops) to identify feasible research objectives for meeting nutritional concerns. The thrust of the discussions was as follows:

The plant breeders said "What do you want? We'll create a plant for you—tell us how much thiamine you want, how much riboflavin, whatever. We can create that plant—with biotechnology we can create it faster than we used to when we had to use very long-term selection techniques."

The animal scientists determined they could produce meat with less fat, and possibly lower fat milk, if only a marketing system existed that would pay the necessary premiums.

Food scientists also said "Tell us what you want. Using agricultural commodities as raw material, we can fabricate the needed food. We could do it—if the regulations on standards of identity and labeling were changed."

And the nutritionists got into the discussion. "Well, on the one hand, maybe; on the other hand..." I have exaggerated a little bit in terms of all the content, but the thrust of these workshops were along those lines. But nutritionists were not able to provide the recipe as well as would have been liked.

It became clear that a better understanding of basic plant biochemistry was needed to determine what was possible and what made sense in terms of agronomic and other characteristics. Looking to the future of modified plants and even animal compositions by means of genetic manipulation, our horizons are very broad, and the time scale is probably short in terms of how long it might take us to get there. As we look to biotechnology to create production systems for future raw materials incorporated into foods, it is not possible to comprehend the scope of what might be produced, or what consumers will accept. It is difficult to foretell what might happen on the basis of nutrition.

A particular food is only a small part of a varied diet, and few people consume a single food as a total diet. When new foods are created it is most appropriate to think about them as new versions of an "old" food, and to examine them within the context of what they would replace. Questions such as: What is the role of the new food in the diet? What proportions of the daily energy does the new food supply? and within that context, What features should this new food have?, are appropriate. For example, most nutritionists do not believe that new foods need to be super fortified with nutrients.

Most likely, guidelines will be necessary to determine what foods new foods might replace. Do new foods have a similar micronutrient profile as foods they generally replace; and can the nutrients within these foods be utilized—are they available, and can they be ingested and metabolized by the people who are consuming them?

If dietary patterns remain the same, will the nutrient profile of the population change, and will that pose a nutritional risk? These are the kind of questions that will be asked by nutritionists as we look ahead to some of the biotechnological advances. For example, as materials such as olestra and other fat substitutes enter the market in foods where they replace ma-



for dietary caloric sources, it will be important to consider how the nutrient profile within the overall dietary pattern is affected.

Changes in plant composition may be more valuable in animal feeding than for humans. The fact that tailored crops will be more available, and more useful for feeding to certain animals, is an very exciting prospect, and will continue to be important.

**...changes, whether through biotechnology or by traditional means, must be viewed in the context of entire food patterns, and not in terms of one food.**

The production of materials of alternate food composition through biotechnology is not cause for alarm. We, as consumers in this country, have a choice whether or not to consume a specific food. This freedom will be an important issue as we look ahead. We will need to look carefully at our regulatory laws to ensure they accommodate these technological advances while still protecting consumers.

It is critical to recognize that we eat a varied diet, and that changes, whether through biotechnology or by traditional means, must be viewed in the context of entire food patterns, and not in terms of one food. With that in mind, those dealing primarily with the nutritional aspects of food could actually be helpful to technologists as they plan food changes. We should take advantage of this great new world of foods that is coming.



## Many Voices: Citizens and the Issues of Biotechnology and Food Safety

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The last couple of years have been incredible ones to be involved in the food business. At no time in memory have the American people had a better opportunity to understand the complexity, the interdependence and the vulnerability of the system upon which all depend for nutrition. The timing of this meeting could hardly have been better.

Biotechnology is a controversial topic, difficult to discuss without provoking heated and divisive debate. My responsibility is to raise some of the issues central to that debate, hopeful that the opportunities encountered in later sessions of this meeting will provide the time to begin to form bonds of common interest that will see at least a few of us moving beyond the poles from which these discussions began. Judging from past meetings on this subject, I confess to being less than optimistic.

This presentation will discuss the issues of food safety and biotechnology from the perspective of the many voices of ordinary citizens. As a consumer, I am a member of that faceless mass known as the general public; an "A" student of citizen movements. I am concerned, among other things, with the issues of food safety and biotechnology. I believe it is important for all to know what this particular voice believes about the way our daily bread is produced, processed, and distributed.

This presentation includes thoughts about the context within which citizens find themselves today and how that context impacts on their attitudes about the food system, the technology that powers it, the public policies and regulatory structures upon which it is constructed.

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**The Minnesota Food Association is a state-level citizens' organization which has identified biotechnology as a technological development of great importance and one much in need of rational, broad-based dialog and policy development activity, at all levels of governance in society.**

Also, the prospective introduction of biotechnology into personal and communal lives and how it affects the picture will be discussed along with some ways of thinking about these matters.

A strong and healthy society requires a food system which:

- produces affordable, safe and nutritious products in adequate supply;
- provides economic return to producers which is fair and adequate to their needs and which encourages their stewardship of natural resources;
- encourages the sustainable development of healthy rural and urban communities, and

—contributes to the equitable distribution of goods, services and opportunities associated with the system.

Over the last ten years, it has become clear that the current food system is not structured to meet the above goals. Rather, it functions primarily to maximize profits with little regard to the social or economic stresses created for citizens who exist at the extreme ends of the system, namely: The primary producers, encouraged by public policies, by technological development, and by market forces to maximize production without regard for other people or for the environment; and the consumers who are encouraged to remain ignorant, to buy cheapness and convenience with little thought for the health effects of those decisions upon themselves; or to the impacts of their buying habits on the social and economic well-being of the people who produce the food; or on the sustainability of the natural resource base required to bring it to their tables.

This system, therefore, does not operate in the long-term interests of the citizens of this nation. However, there are powerful forces at work which derive short-term benefit from this arrangement, and which will undoubtedly resist reform.

The Minnesota Food Association (MFA), along with scores of other citizen groups is pursuing an agenda which will bring about changes in the food system both here in the United States and elsewhere around the globe. If society is to make the changes necessary to bring about a food system which will serve the interests of ordinary citizens, it must: become very smart about the food system; identify which parts of it serve well and which do not; and develop an understanding of the role technology plays

in the system—which particular technologies contribute to the achievement of identified goals, and which do not. Finally, it must recognize that the current system over-values high technology development at the expense of economic justice and ecological well-being, and structures its involvement accordingly in order to bring about change.

It is necessary also to examine the social context in which these issues are to be considered. Most Americans operate with a given set of values, which guide everyday life and provides responses to things encountered in the environment. Most important among these values is the sense of security; security in knowing that basic needs of both individuals and families can be met, security in the predictability of life on a day-to-day basis. This sense of security is reinforced by trusting that the “people in charge”—elected officials, public servants, scientists and academicians are people

**Citizens value the sense of control felt when their role as citizens is fully empowered and respected. Consequently, citizens in a healthy society must be prepared to accept and exercise power—prepared by experience, adequate and accurate information, and by access to the processes through which the rules of governance are made and enforced.**

who can be counted on as: responsive to societal needs of safety and security; fair and competent in the execution of their given duties; and long on vision and courageous in their concern for the future. Citizens value the sense of control felt when their role as citizens is fully empowered and respected.

Consequently, citizens in a healthy society must be prepared to accept and exercise power—prepared by experience, adequate and accurate information, and by access to the processes through which the rules of governance are made and enforced.

This empowerment requires sufficient time and opportunity to engage in debate and dialog with others in the community. People need to feel that there is time to expand their knowledge fully before having to commit themselves on issues which are significant to

the sense of security, trust, and control in their communities.

Food, in particular, has special meaning in the context of these values. The food supply is one of the most basic aspects of personal and family security and community trust. Threats to the reliability of supply, breakdowns in distribution, threats of contamination or toxicity will bring about public responses—rational or otherwise, which are intended to re-establish control and predictability in the system.

Today, most people are completely dependent upon others whom they do not know, processes they do not understand, and institutions they do not trust or control, for virtually every aspect of nutrition. This reality

**Today, most people are completely dependent upon others whom they do not know, processes they do not understand, and institutions they do not trust or control, for virtually every aspect of nutrition.**

greatly affects attitudes toward the food system in general, and sets up a volatile political and social environment.

The sheer scale of the system has created a situation which only recently began to find its way into our thinking. The food system is truly global in scope, the cast of characters changes rapidly, and brings in groups such as LaBatt's Beer from Canada as a major player in the East Coast's dairy business, and Texas oil

men moving into mammoth-scale pig farming in Colorado. One recent merger of two major food corporations involved 100,000 employees and will position the new company to command 10 percent of the American food market—an estimated 22 billion dollars in annual sales!

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The rapid evolution of this system has brought with it a parallel and complex arrangement of government regulatory agencies and rules designed to protect the vulnerable consumer from dangerous additives, contamination by foreign materials and disease organisms, and adulteration by unscrupulous entrepreneurs. This is supposed to defend against the enormous scale and impersonal nature of the food system. Today, there is a widespread perception that the defense system is inadequate, is performing badly and, in fact, seems often to be in conflict with the public's interests by working too closely with those interests being regulated. This is certainly the perception in biotechnology's case.

Over the past few years, the people of this country have been bombarded with reports of:

- inadequate inspections of imported meats and fresh vegetables and other questions about the intent and/or competency of government food safety regulators;
- growth hormones in our meat;
- drug residues in our milk;
- Salmonella in chickens;
- Alar in apples;
- cyanide in grapes;
- resistant strains of human pathogens due to sub-therapeutic doses of drugs in animal production;
- genetically-engineered cross-eyed, arthritic hogs;
- releases of genetically-engineered organisms into the environment;
- patenting of animals

just to name a few. These reports have created a climate of public fear, confusion and suspicion and have served to bring the reality of our dependence and vulnerability home with great clarity.

What does all of this have to do with the issues of biotechnology and food safety? Social science research indicates that the faster the pace of change, and the more complex the proposed change, the greater the resistance to that change by those who perceive it to be a threat to their security. On a scale of one to ten, biotechnology scores near 10 on all counts. People are concerned:

- that food which is grown or processed using biotechnology will not be safe to eat;
- that the system of regulating biotechnology research and testing is inadequate to assure the safety of these new techniques;
- that the application of these new processes will permanently alter and/or damage ecological systems;
- that the motives which drive the rapid commercialization of biotechnology research discoveries will compromise Land-Grant universities, seducing them through the promise of fame and fortune to short-cut their responsibilities for providing citizens with accurate, unbiased information;
- that the high technology, capital intensive aspects of biotechnology will further exacerbate the inequities of the current food system speeding the centralization and control of production resources, reducing real choices for ordinary citizens—all in the name of progress;
- that the prospect of enormous profits will lure people and resources away from other areas of needed and useful research and into short-term, less community-oriented areas of inquiry. For example, research to improve the nutritional quality of food will be sacrificed to that which will make food items more colorful, more flavorful, or more uniform in size, or have a longer shelf-life.
- Finally, people are most concerned about the rapid and unrestrained introduction of this powerful, radically-different technology into today's society—a society in which the hierarchy of science is energized by an almost religious conviction that any problems caused by its short-sighted curiosity and assumptions of dominance can be corrected through more of the same. In other words, society may not be "grown-up" enough to handle the introduction of biotechnology.

What has the response been of the regulatory and scientific community to these concerns? There is little positive to report:

**No voice in the process should be demeaned, ignored or stilled.**

—Concerned citizens are called uninformed, emotional and unscientific zealots by high government officials charged with the responsibility for regulating the industry on behalf of the public. In one specific in-

stance, an official used the term “intellectual pygmies” to describe those people who would question any aspect of biotechnology;

- Citizen efforts to create locally adapted and accountable regulatory mechanisms are threatened by Federal legislation which would preempt their right to set tougher standards than those established at the national level;
- Land grant researchers whose work is being supported by grants from biotechnology companies are appearing in legislative hearings and public events touting biotechnology benefits without balancing considerations of possible problems;
- Legitimate questions about possible unintended outcomes are glibly put aside with assurances that this technology is no different than what has been in use for years in agriculture.

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Responses such as these are familiar to citizens who have been involved in the early anti-nuclear power issue. However, biotechnology is being introduced into a society radically different from the one in which nuclear power was introduced. Citizens have more information and less trust in their institutions, and more experience in organizing and in confronting power. Citizens interests are smarter and better organized. Environmentalists, church groups, animal welfare advocates, hunger organizations and even small groups of scientists and economists are forming networks and coalitions that transcend single issues and national borders.

The so-called “consumer movement” is much more than that. Citizen power is being exercised on many fronts, and there are indications that it is having an impact. The recent action of the Minnesota and Wisconsin legislatures to establish a BGH/BST moratorium is a good example of this impact.

The message is a simple one. We are a society of many voices:

- some rational and reasonable, willing to sit around the table with you and debate the many points of view involved with an issue in a civil fashion;
- some who are motivated by fear and uncertainty, activated by newspaper headlines, confused and randomly powerful as they try to adapt their purchasing behavior to the latest report on diet and cancer;

—and some who see biotechnology providing a public platform from which to speak out and organize the fundamental reform of our food and agriculture system.

The issues being discussed here are far more complex than just a matter of figuring out how to communicate a particular message to consumers.

In a democratic society, the sound of many voices, raised in civil discourse, is a sign of a healthy society, where the search for the right path is a communal process, not simply the exercise of power of one group over another in a win-lose struggle. We all occupy the same planet, deriving basic needs and a sense of community from the same base. No voice in the process should be demeaned, ignored or stilled.





## **Farmer Concerns: Food Safety, Biotechnology and the Consumer**

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### **Introduction**

The goal of this conference is to identify and evaluate the impact of biotechnology on improving the safety and quality of food. At the same time, we have been asked to evaluate the relative safety of foods and food products derived from biotechnology. I am going to approach this issue from a slightly different perspective. Rather than assess the potential of biotechnology, I will focus on how farmers can more effectively deal with the concerns of consumers over food safety and biotechnology. Without consumer backing, biotechnology products face a bleak future.

First is a review of two recent public opinion surveys on food safety and on biotechnology. The first survey indicates that consumers want farmers to speak out about food safety issues. The second survey indicates that both consumers and farmers need more information about biotechnology. On the basis of these survey results, strategies will then be discussed. To strengthen the link between farmers and consumers to prepare the public for the introduction of biotechnology products, two goals will then have to be accomplished. First, farmers' awareness of biotechnology must be increased. Secondly, means must be developed which allow farmers to speak directly to consumers about the farmer's needs and how biotechnology products fit into their farming operations.

### **Public Attitudes Towards Farmers and Food Safety**

Recently, the American Farm Bureau Federation took steps to determine more precisely the public's attitudes towards farmers and food safety. Working with the

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public relations firm of Porter/Novelli, the consumers' image of farmers, their current awareness of food safety issues, and their perceptions about the involvement of farmers in these issues were examined.

To accomplish our objectives, a nationwide telephone survey was commissioned by National Research, Inc., a market research firm located in Washington, D.C. Interviews were conducted by telephone between January 4 through 10, 1990. A total of 1,200 interviews were completed. Among our findings:

### **Farmers and Food Safety**

In their attitudes toward farmers, nine out of ten respondents (93 percent) believed farmers are "trustworthy" and 56 percent felt that farmers are "very trustworthy". The majority (88 percent) agreed or strongly agreed (45 percent) that "farmers are doing a good job of producing healthy food". Men (51 percent) and those over 50 (52 percent) were more likely than women (39 percent) or age groups between 18-49 (40 percent) to highly praise the efforts of farmers.

However, the public was less convinced that farmers are conscientious about protecting food safety and the environment. While four out of five (79 percent) agreed that "America's farmers are very concerned about the safety of the food they produce", only one third (34 percent) agreed strongly. Consumers living in the West were less inclined than their counterparts to perceive farmers as being very concerned about food safety.

### **Family Farms and Corporate Farms**

Two out of three respondents (63 percent) believed that most of our food is produced on large corporate farms. "Corporate farm" believers tended to reside in the West, have incomes over 50,000 dollars, and be somewhat more distrustful of farmers. They were more concerned than other respondents about pesticides and hormones in farm products. In contrast, the third (32 percent) who believed family farms produce most of the food eaten were more likely to live in the Midwest, have incomes under 20,000 dollars, and consider farmers to be "very trustworthy". The actual structure of agriculture differs from these perceptions and is reviewed in the Appendix (see p. 114).

The public also felt that the "family farmer" (upon which their positive image is based) is rapidly disappearing in favor of large, impersonal, "corporate" farms. "Corporate" farmers were characterized as relatively uncaring business executives. Their "intelligence" and sophistication may be greater, but their trustworthiness related to food safety issues is quite suspect.

Corporate farms were credited as being chief suppliers of food in large grocery stores and as heavy users of agrichemicals. Conversely, small farmers were described as caring, honest and less likely to use agrichemicals, seen chiefly as suppliers of food for local and pick-your-own markets.

Most believed corporate farms were more likely than family farms to "use sophisticated equipment" (90 percent), "adopt new and improved farming methods" (66 percent), and "be more efficient and productive" (59 percent). However, though the public acknowledged the sophistication of corporate farms, it doubted their ability to produce safe and wholesome food. Compared to corporate farms, the public was more likely to trust family farms to "produce foods of higher quality". (72 percent), "use chemicals safely" (70 percent), and "respond to consumer concerns and desires" (62 percent). The perceived trustworthiness and caring of the "family" farmer appeared to be more important than the intelligence and sophistication of the corporate farmer when the issue was safe use of farm chemicals.

### **Food Safety Concerns**

Most of the concern over food safety centered around the use of agricultural chemicals. Consumers were more concerned about pesticides (89 percent) than other food issues such as spoilage (85 percent), fat and cholesterol content (82 percent), additives and preservatives (80 percent) and hormones (77 percent). Overall, women were more concerned than men about food issues. Older consumers (60 percent) expressed more concern about pesticides than their middle (54 percent) or younger (48 percent) counterparts. Consumers with a high school education or less (59 percent) were more concerned than those who had more education (49 percent).

However, consumer concern had minimal impact on consumption. Only one out of three consumers (36 percent) avoided foods because they thought those foods might be harmful to their health.

**Only one out of three consumers (36 percent) avoided foods because they thought those foods might be harmful to their health.**

In general, the survey found that consumers were "chemophobic". That is, they were fearful, confused and concerned about the use and possible misuse of farm chemicals. Farm chemicals were primarily perceived as harmful tools used for financial gain. This perception is particularly disturbing in view of a recent study which documents how damaging this kind

of chemophobia could be on the quality and quantity of our food supply if carried to extremes (Knutson et al., 1990).

### **Getting Farmers Involved**

The food safety survey showed that the public strongly supports farmers having a proactive voice in the food safety issue. Most felt that farmers should speak out more forcibly about their views on food safety issues (94 percent), provide consumers with information about all the chemicals they are using (93 percent) and educate consumers about their farming practices (89 percent).

### **Public Attitudes Towards Biotechnology**

Because few products have reached the market yet, it is difficult to gauge public concerns over biotechnology. It is obvious, however, that biotechnology is evolving under intense public scrutiny.

Late in 1988 and early in 1989, the North Carolina Biotechnology Center and the North Carolina Agricultural Extension Service undertook an educational needs assessment of agricultural biotechnology (Hoban and Woodrum, 1990). Telephone interviews were conducted at random with rural non-farm consumers, urban consumers, and farmers in North Carolina. In addition, information about biotechnology was also collected from agricultural leaders through interviews and mail surveys. The results provide a snapshot of one state's attitudes towards biotechnology. For survey purposes, biotechnology was narrowly defined as genetic engineering.

### **Awareness of Biotechnology**

**However, only one-third of the farmers had heard of how genetic engineering might change their farming operations.**

Public awareness of genetic engineering in North Carolina in 1989 was low. Slightly more than one-third of the people reported they had read or heard something about it. Almost half said they had heard only a little about it. The remainder (13 percent) had heard nothing about it. Awareness was highest among urban residents and those who were younger, better educated and more affluent. Farmers were more aware of genetic engineering than were rural non-farm residents. However, only one-third of the farmers had heard of how genetic engineering might change their farming operations. Most of the information on genetic engineering had been gleaned from the mass media.

### **Desirability of Biotechnology**

Respondents were in favor of most genetic engineering applications. Producing more nutritious food was cited as a very desirable use of agricultural genetic engineering (77 percent) with frost-resistant plants (58 per-

cent), insect-resistant plants (53 percent), and herbicide-resistant plants (41 percent) also scoring high. On the other hand, only one third of the respondents said that genetic engineering to produce larger or faster growing livestock was very desirable. Those who were most favorable towards genetic engineering included people with higher incomes and more education. Younger respondents and men were also more favorable.

Attitudes towards genetic engineering of plants as compared to animals differed. Only 12 percent of respondents thought plant genetic engineering

**Consumers expressed greater concern about eating genetically engineered meat and dairy products than they did about genetically engineered fruits and vegetables.**

was morally wrong. Rural non-farmers were most likely to feel this way and farmers were least likely. However, 38 percent of all respondents felt genetic engineering of animals was morally wrong. Again, non-farmers were more likely to feel this way and farmers least likely. About 16 percent of the respondents did not have an opinion about the morality of engineering either plants or animals.

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### **Food Safety Concerns**

Consumers expressed greater concern about eating genetically engineered meat and dairy products than they did about genetically engineered fruits and vegetables. One-third of the non-farm respondents said they would be very concerned about eating genetically engineered fruits and vegetables and 43 percent said they would be somewhat concerned. Twenty-three percent said they would not be concerned. Rural non-farm residents were significantly more concerned than were urban residents or farmers. When asked about eating genetically engineered meat or dairy products, most respondents answered that they would be either very concerned (45 percent) or somewhat concerned (37 percent). Only 18 percent of the consumers said they would not be concerned. Our current diet contains hybrid fruit and vegetables and meat and milk from hybrid animals but 33 percent of consumers were not aware of this.

Farmers in the survey were asked how concerned they thought consumers would be about eating genetically engineered food. When asked about

**Agricultural leaders tended to underestimate the level of consumer concern over genetically engineered products.**

genetically engineered fruits and vegetables, one-third (35 percent) thought consumers would be very concerned, one-half (48 percent) thought they would be somewhat concerned, and 13 percent thought consumers would not be concerned. Their perception of consumer concerns about genetically engineered meat

and dairy products was similar. Agricultural leaders, however, tended to underestimate the level of consumer concern over genetically engineered products.

### **Conclusions From Survey Results**

These two surveys tell us the following:

1. Consumer concerns over food safety remain high, especially regarding pesticide residues. This concern, along with the lack of knowledge about biotechnology, raises the possibility that consumers could react negatively to food produced by biotechnology.

2. The public perceives two distinct types of farmers, "family" and "corporate." Family farmers are seen as caring and honest. Corporate farmers are regarded as smarter, more innovative, better trained but basically uncaring. The public believes that American agriculture is becoming dominated by large corporate farms which mainly supply big grocery store chains. Given this belief, it is not surprising that one of the most controversial issues in biotechnology centers around the potential impact of these products on small family farms.

3. The public regards farmers as a credible source of information on food safety. Consumers are eager to hear from the farm community. However, at this point, most farmers do not yet know enough about biotechnology to talk to consumers.

Given these findings, where do we go from here? If we believe that biotechnology promises many potential benefits for farmers and consumers, we have to work towards two goals. First, we have to raise the awareness level of farmers about biotechnology. Secondly, we have to provide the means for farmers to speak out to consumers about what farming looks like and how these technologies might be used on their farms.

### **Increasing Farmer Awareness**

Farmers need to know more about biotechnology to adopt these products successfully and to interpret the impacts of these technologies on food production for themselves and for consumers. In general, farmers will adopt the products of biotechnology in much the same way as they have other farm technologies. Knowing this, we can design programs to reach all segments of the farming community (Hoban, 1989).

Basically, farmers adopt new technologies by going through a five step process. First they become aware that a new product exists. This leads to an interest in finding out more about it. They then try it out on a small scale to see if it will work on their farm. They evaluate the results and, if

they like what they see, they adopt it for the next growing season. Because of economics, early adopters often make the greatest profit. A profile of an early adopter would look something like this (Hoban, 1988):

A commercially successful operation, large-scale and more specialized than the normal farming operation; is a sophisticated financial manager, relying on credit; looks at farming as a business rather than a way of life; tends to have more formal education; is often more capable farm and business manager who is highly motivated, willing to take risks, well connected to communication networks, and tends to be a community opinion leader.

In addition, farmers who respond well to biotechnology are younger than the average farmer (who is 52 years old), better educated (college or beyond), newer to agriculture, and farm more acres with a higher gross income (Bultena and Lasley, 1987). An average farmer is described in the Appendix (see page 14).

In most cases, early adopters will probably not be the "family farmers" that the public wants to protect. We can minimize the adverse impacts on these farmers by working towards improving their management skills. Indeed, to more easily integrate technological advances, most farmers will need better management skills in the future (Kalter, 1985). According to the North Carolina survey, in early 1989 only one-third of their farmers had heard of how genetic engineering might change their farming operations. Most indicated that they would like to receive much more information about genetically engineered products before they are marketed.

**To learn about biotechnology, farmers will continue to rely heavily on information from the Extension Service.**

The best way to reach farmers is through a variety of sources. Four sources that come immediately to mind are the Extension Service, the farm and commodity organizations, professional consultants and farm publications.

**Extension Service**

To learn about biotechnology, farmers will continue to rely heavily on information from the Extension Service. They will be particularly receptive to information presented by university researchers at local meetings (Thomas J. Hoban, personal communication). As the primary source for information, the Extension Service needs to be sensitive to the uniqueness of concerns surrounding biotechnology (Sorensen, 1989). The following suggestions are offered as possible ways to address these concerns:

- Extension could increase efforts to assist limited resource farmers in expanding their management skills.

—Extension could play an expanded role in conducting on-site tests to determine if new crops or products are well-suited to local conditions.

Companies may not have the resources or incentives to do this. A potential problem is whether or not Extension agents will have access to innovations before they are marketed to farmers (Buttel, 1987).

Dr. Thomas Hoban (1989) presents a strong case for making social science research available to Cooperative Extension Service directors, research administrators, and public policy makers who are interested in evaluating and mitigating the impacts of technology. In particular, there are three areas of inquiry worth exploring:

Technology assessment tries to identify a wide range of social, political, economic, and environmental consequences that may result from technological change before they happen. Like cost-benefit analysis it weighs beneficial consequences against adverse impacts (Molnaret al., 1987).

Social Impact Assessment includes another related set of useful tools and ideas that could help identify, evaluate, and deal with negative impacts of new technologies (Freudenburg, 1986). Public participation and education play an important role in this type of assessment.

Interorganizational Relationships attempts to analyze relationships among organizations and develop mechanisms to insure efficient and equitable collaboration with optimum resource exchange (Rogers and Whetten, 1982). We will need coordination and cooperation from the universities, the Extension Service, and the private sector if the transfer of new technologies is to be successful.

### **Farm and Commodity Organizations**

General farm organizations and commodity organizations can also serve as conduits for information about biotechnology. For example, the American Farm Bureau Federation has made biotechnology one of its priority issues. Workshops on biotechnology have been held at Farm Bureau national meetings, state meetings, and county meetings for the last four years. State and county Farm Bureaus are encouraged to:

- Identify biotechnology research within the state and develop a list of contacts for information. Establish information sources both within industry and within the academic community.
- Identify state legislators who have shown an interest in biotechnology legislation. Notify them if regulations will affect farming operations.
- Make use of free information from the USDA including their newsletter and electronic bulletin board on agricultural biotechnology.



- Keep track of local zoning and environmental statutes. These are important determinants of policy that may affect future tests and applications.
- Help educate the public about farming practices and the need for and impact of new agricultural technologies. Work with Agriculture-in-the-Classroom coordinators to introduce these issues into schools. Participate in the Adopt-a-Scientist program. Identify effective spokespeople that can answer questions on biotechnology and farm issues. (These recommendations are explained in more detail in the next section).

### **Professional Consultants**

Professional consultants represent another loosely defined group that will be important in technology transfer. They will probably work more closely with early adopters than will Extension agents because of resource limitations within the public sector. The demand for qualified experts will grow as more products and increasingly sophisticated technologies become available.

Over the last few years, representatives of several scientific societies have worked to develop a concept of integrated certification for agricultural and environmental professionals. The Board on Agriculture, part of the National Academy of Sciences' National Research Council is currently exploring the possibility of examining the potential benefits of a registry and certification process for professionals engaged in the delivery of technical services and advice to farmers. Their efforts are supported by the National Association of Independent Crop Consultants.

### **Farm Publications**

Farm publications also have an important role in getting information out to the agricultural community. We have seen a sharp increase in the number of articles about biotechnology in the last few years. Most articles are speculative in nature but serve to prepare farmers for the wide variety of products and potential concerns. As products become more widely available, specialized trade journals and Extension publications can give pointers to farmers on how to make use of them.

**Once farmers have learned more about biotechnology, we will have to provide the means whereby they can speak out on these issues.**

### **Linking Farmers to Consumers**

Once farmers have learned more about biotechnology, we will have to provide the means whereby they can speak out on these issues. Since I am

most familiar with what the Farm Bureau is doing, I will review our programs as examples of ways in which we can improve the communication links:

1. Involving farmers in the early stages of biotechnology research will give both the researchers and farmers a better idea of what is needed and what to expect. The American Farm Bureau Federation started the Adopt-a-Scientist program in 1988. It was developed to improve communications and the flow of information between scientists and farmers. The exchange program places leading scientists on farms across the United States and provides the host families an opportunity to visit the scientist's lab. More importantly, the program opens a dialog between scientist and farmer. The scientist visits his or her host family before planting, during the growing season, and at harvest. Each visit lasts two to three days. Scientists chose which crops or livestock and which area of the country they want to visit and are then matched with a farm family. In the inaugural year, nine scientists from three companies teamed up with farm families in eight states. In 1989, the program involved 18 scientists from nine companies. This year, there are 27 scientists gearing up to visit 14 states. At present, the program is limited to scientists from private industry. However, several universities have expressed an interest in participating as well.

2. Increasing the public's awareness of current farming practices has to be a priority. One of the most successful efforts is Ag-in-the-Classroom, a program developed by the USDA to teach children in our schools about agriculture. One component of the Ag-in-the-Classroom curriculum is a section on new technologies in agriculture. These programs offer an effective way to familiarize young consumers with agricultural biotechnology.

Farm Bureau has developed a parallel program called Agriculture-in-the-Classroom that compliments the USDA effort and adds a state perspective to the material. Along with videos, brochures, and coloring books designed by state Farm Bureaus, states have developed programs to educate school administrators, state policy decision makers, and others who provide input to the public about agriculture.

3. Developing effective spokespeople for the agricultural community is another priority. Farm Bureau is currently offering spokesperson training. These workshops include a session on presentation excellence aimed at improving presentation skills. It focuses on how to improve delivery techniques, gain audience attention, and use visual aids effectively. Participants also attend a media workshop. Skills learned include an understanding of the print and electronic mass media, how to develop and deliver a message and how to anticipate questions.

4. Identifying appropriate forums for farmers to reach consumers is a bit more difficult. County and state fairs offer an opportunity for farmers to inform consumers in friendly surroundings. Local civic organizations which hold regular meetings are also a good way to exchange information. Some of our state Farm Bureaus are now helping to underwrite local public television station programs on agriculture and the environment. Through Agriculture-in-the-Classroom, some states offer farmers an opportunity to adopt-a-classroom. Writing letters to the editor of the local newspaper is another way of getting a message heard. Developing contacts with the local media, both television and radio reporters, and maintaining those contacts by providing reliable and credible information is also effective.

## Conclusions

Farmers have always been concerned about providing safe and nutritious food to the consumer. However, following the revelations about possible pesticide residues and hormones in our food supply, this message has fallen on hard times. The lack of public understanding about modern farming practices is approaching a critical test. In the next few years, farmers will have to make choices about products resulting from biotechnology. These technologies are poorly understood by the public but they may have a profound effect on farming. Farmers have to do a better job of telling their story. We can begin by giving farmers as much information as possible about biotechnology. Once they decide how these products will affect them, they can then convey their needs and concerns to consumers.

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## Appendix

### The Current Farming Sector

The United States Department of Agriculture defines a farm as any place that sells, under normal circumstances, at least \$1,000.00 of agricultural products in a year (U. S. Department of Commerce, 1989). Almost all of our farms are family-owned. About 3 percent of all farms are organized as corporations and almost all of these are family-held. Only 0.3 percent of farms are owned and operated by a unit other than a family. Eighty-seven percent of our farms are owned and operated by a single family. The remainder are operated as multifamily partnerships.

The 6,000 non-family corporate farms account for about 6 percent of farm output (Mazie and Carlin, 1990). Despite fears that this form of farm-

ing is gaining ground, non-family corporate farming did not change as a percentage of all farms during 1982-1987. The long-term trends of declining farm numbers and land in farms, coupled with increasing farm size, did continue through the 1980s. At 2.1 million, the 1987 farm count was down 6.8 percent from 1982. Forty-nine percent of these farms had gross sales of less than \$10,000, 36.5 percent grossed between \$10,000 to \$99,999, 12.6 percent grossed between \$100,000 to \$499,999, and 1.5 percent grossed over \$500,000 (U.S. Department of Commerce, 1989). While fewer in number, hobby farms increased as a proportion of all farms during the 1980s. The number of farms with \$10,000 to \$100,000 gross sales decreased in both absolute and relative terms. The proportion of large farms, which produce the bulk of U.S. food and fiber, continued to increase.

Looking at commodity sales, in 1982, small farms (grossing less than \$10,000) contributed only 2.7 percent of sales, small family farms (between \$10,000 to \$39,999) 8.2 percent, family farms (between \$40,000 to \$249,999) 41.5 percent, large family farms (between \$250,000 to \$499,999) 15.1 percent, and very large farms (gross sales over \$500,000) contributed 32.5 percent to commodity sales (Reimund et al., 1986). By 1988, the 4.9 percent of our farms with sales in excess of \$250,000 produced 54.6 percent of all cash receipts (Congressional Budget Office, 1990).

Higher yields from larger farms are attributed to several factors (Reimund et al., 1986). First, large farm operators may employ better management and cultural practices than operators of small farms. Secondly, larger farms have better quality resources than smaller farms. And thirdly, larger farms are located in areas better suited to the production of a specific commodity. If you ask farmers about the size of farms to come, they often conclude that as technology improves, they will have to farm more acres to stay competitive (Waterloo, 1990).

Slightly less than one-quarter of all farms fall between the small farm and large farm categories (Congressional Budget Office, 1990). The growing predominance of small farms, in terms of numbers, and large farms, in terms of production, raises concerns about whether these family-sized farms can survive. Many of the 537,000 farms in this middle group are sufficiently large to require a full-time manager-operator. This probably rules out off-farm employment as a source of additional income. It is not clear whether these farms are large enough to realize economies of scale in production, marketing, and finance as mentioned above (Congressional Budget Office, 1990).

The average farm in the United States is now 462 acres. This is a five-percent increase from 1982. About 22 percent of our farms grow cash grain, 11.7 percent grow field crops, 7.1 percent grow vegetables, fruits, and landscape plants, 6.6 percent are dairies, 1.9 percent are poultry farms, 42.8 percent raise other livestock, and 8 percent are classified as "other." (U.S. Department of Commerce, 1989). Last year, 15 to 20 percent of U.S. farm output was sold abroad (Mazie and Carlin, 1990).

For 55 percent of people living on our farms, the principal occupation is farming. Thirty-five percent work 200 or more days off the farm to supplement their income. The average age of the farm operator is 52 years old. Fifty-percent of our farms are in the Midwest, 14.6 percent in the West, 29.6 percent in the South, and 5.2 percent in the Northeast (Dunn and Walmer, 1989).

In 1988, the mean U.S. household money income was \$34,017. The level of farm assets required to generate a \$30,000.00 cash income for a farmer varies with the type of farm. For example, a corn-soybean farmer would have to invest \$429,000 for a \$30,000 return; a wheat farmer, \$600,000; a cotton farmer, \$300,000; a tobacco farmer, \$214,000; a hog farmer, \$375,000; a dairy farmer, \$600,000; and a cattle rancher, \$1,000,000 (Dubman and Hanson, 1987).

Most of our farms do not produce government-supported program commodities and, among those that do, not all participate for one reason or another (Mazie and Carlin, 1990). Nationwide, about one in three farms received some of \$14.5 billion in direct government payments made in 1988. Participation varies by size and type of farm, and by location. For example, 90 percent of cotton farms reported receiving payments in 1988, while 49 percent of dairy farms reported payments. Participation in government programs is highest among producers in the Northern Plains, Corn Belt, and Lake States. Recipient farms reported average payments of \$14,300. Government payments helped participating farm families stabilize their financial situation during the financial stress and debt restructuring of the 1980s.

Farming now dominates the economy in less than one-fifth of all U.S. counties (Mazie and Carlin, 1990). Those who argue that keeping the farm sector strong will preserve rural America must realize that this now applies to only a few rural places. In the majority of rural communities, farming is no longer the cornerstone of the local economy. Except for meat packing and processing, much of the farm input and processing employment has also moved away from local communities as well and is now based in met-

ropolitan areas. This means farm policy is no longer synonymous with rural policy.

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## Biotechnological Diagnostics for the Detection of Microbial Contamination of Food

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Food microbiology plays a critical role in providing consumers with a safe food supply. Foodborne illnesses are estimated to affect as many as 81 million people per year in the United States and to cost the American economy 40 billion dollars per year (Miller, 1990). The challenges of detecting pathogens in food matrices are substantial. A single organism in a 25 gram sample of food has the potential of growing to levels that can cause human illness. Recovery of these organisms in the laboratory is complicated by the fact that they may have suffered sublethal injury from heat, cold, drying or preservatives used in food processing. Since food is rarely a sterile medium, competition from other microorganisms can complicate isolation of pathogens as well. Because of the requirements on food quality control laboratories to provide accurate results for safe product release, assays for food pathogens must be rapid and should involve minimal training. Classical microbiology relies on the growth of pathogens in broths and on agars for presumptive identification. Other techniques are then applied to isolated colonies to determine the exact identity of suspect organisms. Although such techniques are the "Gold Standard" of food microbiology, they suffer from a number of limitations. Because food often contains non-pathogenic microorganisms that are closely related to important pathogens, appearance and biochemical reactions of these nonpathogens can mimic those of their more dangerous relatives. Highly trained personnel are thus needed to make these critical distinctions. Classical procedures are also very time consuming. It can take five days to several weeks to determine if food is free of certain pathogens. (Doyle et al., 1988)



**Foodborne illnesses are estimated to affect as many as 81 million people per year in the U.S. and to cost the American economy 40 billion dollars per year (Miller, 1990).**

Analytical procedures derived from biotechnology research have had a substantial impact on human health care in the past ten years. Assays based on monoclonal antibodies are commercially available for a wide range of drugs and hormones. Application of such assays to food microbiology has been slower to evolve for a number of reasons.

As outlined above, the problems of analysis of pathogens in food is quite complicated. An additional complication is the level of sensitivity required. Direct detection of a single organism in 25 grams of food is beyond the capabilities of even the best present assays and is likely to remain so for a number of reasons. All current biotechnology assays, therefore, require the cultural enrichment of pathogens to certain levels before they are detected. Detectable concentrations for both antibody based assays and DNA probe assays is about a million organisms per milliliter of enrichment broth. Most current procedures take two or more days to achieve this level, but efforts are underway to abbreviate this period without sacrificing assay sensitivity. This sensitivity level of a million organisms per milliliter is not a trivial task.

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**Table 1** Analyte Concentration

Target	Concentration (moles/L)
Glucose	10 <sup>3</sup>
Theophylline	10 <sup>-5</sup>
hTSH	10 <sup>-11</sup>
1,000,000 E. coli/ml (rRNA)	10 <sup>-12</sup>
100 Hepatitis A/ml	10 <sup>-6</sup>

Table 1 shows a list of clinically relevant analytes typically determined by immunoassay and the target levels provided in a broth containing a million organisms per milliliter. Assays for human thyroid stimulating hormone (hTSH) are the most sensitive assays done in the clinical immunoassay laboratory today. Antibody assays targeting antigens with copy numbers of 10,000 per cell and DNA probe assays that target ribosomal RNA at the same copy number per cell must therefore be an order of magnitude more sensitive than these hTSH assays. Assays targeting viral agents where no ribosomal RNA is available must be even more sensitive.

Biotechnology assays face several design hurdles that must be overcome. Increasing target levels to detectable levels has already been discussed in the context of cultural enrichments. For probe assays, there is also a tantalizing opportunity for in vitro amplification. Because nucleic acids have evolved to be copied in order to transmit their information to the

**These techniques are so sensitive that it is likely that they will detect dead microorganisms in food that are of little significance.**

next generation or to the next process in a cell, very efficient enzyme systems exist in nature that can very rapidly produce millions of exact duplicate copies of an original nucleic acid sequence. These enzyme systems have been harnessed to provide nucleic acid amplification schemes to enhance the sensitivity of probe assays. The best known of these is a procedure known as the polymerase chain reaction (PCR) (Saiki et al., 1985). It can amplify a target sequence a million fold in several hours. More recent discoveries have lead to a system based on an enzyme called Q-beta replicase that can amplify probe signals by a billion fold in as little as 15 minutes (Lomelli et al., 1989).

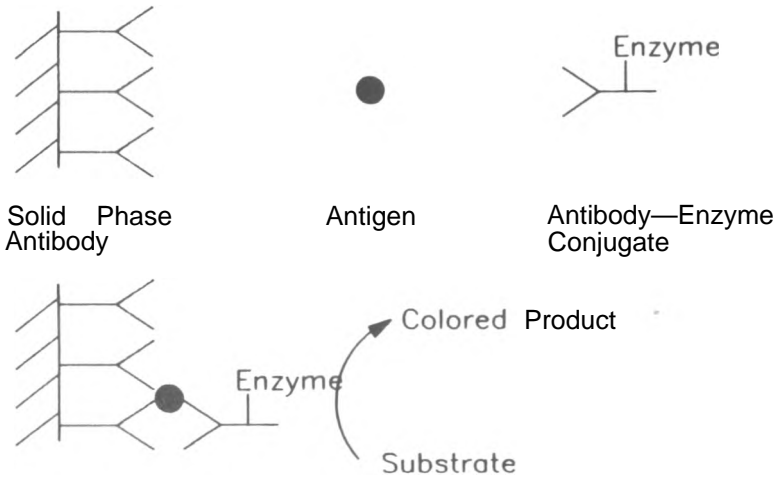
Application of the amplification technologies to food microbiology will, however, be limited by several problems that are related to the very sensitivity that makes them so attractive. These techniques are so sensitive that it is likely that they will detect dead microorganisms in food that are of little significance. The other issue that will need to be dealt with is the potential for cross contamination (Kwok and Higuchi, 1989). These detection systems are so sensitive that even the slightest cross contamination of a negative sample with materials from a positive sample can lead to a false positive result. It is most likely that nucleic acid amplification will be used to shorten enrichment times rather than to replace cultural enrichments altogether. The cross contamination issue will probably be minimized with automation.

Sample preparation is the next hurdle in the design of biotechnology assays. Bacterial antigens must be released from cell walls or internal structures so that they can bind to the detecting antibodies. Heating aliquots of the terminal enrichment culture in a boiling water bath is a common approach (D'Aoust and Sewell, 1988). Nucleic acids targets can be freed from the intracellular matrix of bacterial cells by treatment with strong base or by enzymatic processing, thus eliminating the need for a boiling water bath.

All of these processes also kill pathogens, thus providing a level of biosafety for the operator. Inherent in all high-sensitivity biotechnology as-

says are a separation step in which label bound to some solid phase as a result of the presence of target is separated from unbound label. Solid phase supports are usually made of plastic and facilitate the wash steps that enhance signal-to-noise ratios. Most immunoassays use a microtiter plate as a solid phase. Ninety-six wells that can hold approximately 0.3 milliliters are arranged in an 8 by 12 array. The wells are coated with a capture antibody by the manufacturer. The assay is run by adding the sample to a well and then adding the antibody-enzyme conjugate. If the desired antigen is present, it will be bound by the antibody on the well and the antibody-enzyme conjugate in solution will in turn bind to the antigen. This results in an antibody-antigen-antibody “sandwich” that forms only when antigen is present. Unbound antibody-enzyme conjugate is washed away and enzyme is detected as described below. A schematic representation of this format appears as Figure 1.

## Sandwich Immunoassay



**Figure 1** Antigen is released from cultured organisms by boiling. Solid phase antibody and solution phase enzyme labeled antibody react with antigen, if present. After a wash step, the amount of enzyme present is proportional to the amount of antigen present initially. Enzyme is detected by reaction with substrate and chromogen to produce color.

The DNA probe assays that are produced by GENE-TRAK Systems are based on another type of "sandwich". Target nucleic acid is allowed to react with two different probes in a test tube. These synthetic probes are exact matches for areas of the target that are fairly close together. One probe (reporter probe) is labeled with fluorescein and the other (capture probe) has a homopolymer tail of polydeoxy-

**The future of food microbiology has been brightened by the emergence of biotechnology diagnostic assays.**

adenylic acid (dA). The target and these two probes form a probe-target complex. A plastic dipstick coated with the matching homopolymer polydeoxythymidylic acid (dT) is placed in the test tube. Any probe or probe-target complex that contains a poly dA tail is captured on the dipstick. A subsequent washing step removes any unbound material including fluorescein-labeled reporter probe not bound in a probe-target complex. The dipstick is now incubated with an antibody-enzyme conjugate which binds to any fluorescein residues present. Since the fluorescein-labeled reporter probe can only be present at this point as part of a probe-target complex, the amount of antibody-enzyme conjugate bound is proportional to the amount of target initially present. A second wash step removes unbound conjugate. Exposure of the dipstick bound enzyme to an appropriate substrate chromogen mixture produces a blue color in direct proportion to the amount of enzyme present on the dipstick. Removal of the dipstick and addition of dilute sulfuric acid stops the enzymatic reaction and intensifies the color, completing the assay. The results are read in a differential photometer at 450 nm. The entire reaction scheme appears as Figure 2.

To ensure that the assay has been carried out correctly, two controls are run with each assay, a positive control and a negative control. Both controls must meet certain criteria for the assay to be considered valid. Samples that read 0.1 O.D. units above the negative control are considered presumptively positive for the organism in question.

DNA probe assays target the most fundamental level of information in a cell (Parsons, 1988). The practical significance of this fact is that they produce a better quality result in a shorter time. Table 2 illustrates the time savings possible with the use of our current generation Salmonella assay. Additional improvements in time frame to result are being actively researched. In addition, the quality of the result is also significantly better. One of the more dramatic examples of how much better these results can be was recently provided by some results of our quality control depart-

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# DNA Probe Assay

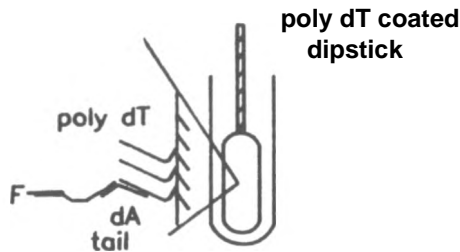
## 1. Sample Lysis

NaOH  
Sample — rRNA

## 2. Solution hybridization

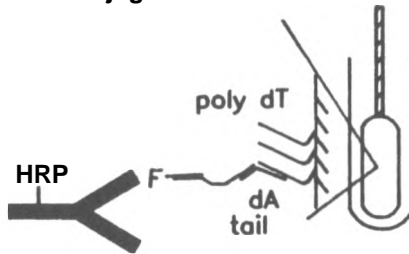
Reporter Probe — F — dA  
Capture Probe — dA  
Target rRNA

## 3. Capture



## 4. Wash

## 5. Addition of HRP—conjugate



## 6. Wash

## 7. Add chromogen/substrate

## 8. Incubate and add stop reagent

## 9. Read color at 450 nm

**Figure 2** After organism lysis to expose the intracellular nucleic acid, the target nucleic acid is reacted with two probes to form a probe-target complex. The dA tail on the capture probe allows capture of this complex on a dT coated dipstick. Detector probe in the complex is detected with an antibody-enzyme conjugate. After a wash step, enzyme present is proportional to the amount of target nucleic acid initially present. Enzyme is detected by reaction with substrate and chromogen to produce color.

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ment. We participate in a Check Sample program provided by the American Association of Cereal Chemists (AACC) (Sail et al., 1988). Every eight weeks, this organization provides the subscribers of this Check Sample program with two unknown samples of flour or flour-based bakery mixtures. These samples may contain *Salmonella*, *Staphylococcus aureus*, *Escherichia coli* and/or other organisms of interest to food microbiologists. Alternatively, they may also be free of such organisms. Each subscriber laboratory tests these samples to the best of their ability and returns their results to the AACC under their own individual code number. The AACC then tabulates the results and reports the results by code number to assure anonymity. Only AACC and the respondent know their own code number. One can, however, compare one's own results against the results obtained

Table 2 *Salmonella* Microbiology

Steps	Conventional	Probe
Primary enrichment	18-24 hours	18-24 hours
Selective enrichment	6 hours	6 hours
Final enrichment	18 hours	18 hours
Plating	18-24 hours	—
Biochemical ID	5-24 hours	—
Serology	4 hours	—
Assay	2.5 hours	
Total Time	72 hours 95+ hours for a positive)	48-52 hours

by all of the other respondents. Since our colorimetric *Salmonella* assay was available in internal pilot lot form, we have been running these Check Samples in our *Salmonella* test. Our results represent perfect agreement with the stated AACC results for the entire duration of the present study with one exception. Despite exhaustive efforts, we were unable to find any viable *Salmonella* in the samples received in January of 1989. Twenty-two percent of the other respondents also reported an apparent false negative. We believe that there may have been a sampling problem with that particular Check Sample series or that there may have been some die off of the inoculated organisms.

What is striking about this study is the occasional spikes of high rates of false negatives experienced by other participants in this program. False negative rates have run as high as 38 percent for one recent sample. Al-

though we do not know the identity of any of the other participants in this study, their participation in such a check sample program speaks eloquently to their commitment to very high quality food microbiology. We believe that these results speak to the limitations of conventional food microbiology which is still used by a vast majority of the industry at this point. An assay such as ours removes the subjectivity and extensive work with various media to avoid missing biochemically atypical strains. These results are reported in greater detail at the Institute of Food Technologists (IFT) meeting in Anaheim, CA (McKenzie et al., 1990).

The future of food microbiology has been brightened by the emergence of biotechnology diagnostic assays. Time to results have been shortened and the quality and universality of results has been improved by the current generation of tests. Yet there remain additional challenges. Tests for additional pathogens and spoilage organisms are in development and will make their appearance on the market in the next few years. Enrichment periods must become shorter to give even faster turnaround times. Minimal enrichments of 4-12 hours will probably always be necessary to avoid detection of dead organisms.

In vitro amplification methods will extend the range of present techniques so that viral agents such as Hepatitis A and Norwalk agent would be detectable in amounts sufficient to cause human disease. Agents causing diseases such as scrapie and bovine spongiform encephalopathy have the potential for causing serious economic loss (Holt and Philips, 1988). Amplification technology will provide the tools necessary for rapid, reliable detection of these agents as well.

Automation of these tests will also become important in the next decade. As more biotechnology pathogen tests become available, the volume of testing will mandate the implementation of cost effective automation to streamline and standardize testing in food microbiology laboratories.

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## Genetically Engineered Plant Foods: Tomatoes

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Calgene is a leading United States plant biotechnology company organized in 1980 to develop and commercialize new crop varieties and plant products developed through the use of biotechnology. Plant biotechnology offers the opportunity for both the proprietary protection of genes which are isolated and patented, and the development of new plant cultivars which are produced using these genes. In some cases, researchers will be able to develop multiple products from a single gene, while in others the developmental cycle of new plant products will be shortened given the tools of biotechnology. Calgene currently focuses on three crops: rapeseed for use in the production of both edible and industrial oils; cotton for improved fiber quality, herbicide safening and insect resistance; and tomatoes for both the fresh and processing markets.

The work described here presents the current status of Calgene's anti-sense polygalacturonase tomato. Polygalacturonase (PG) is a pectin-degrading enzyme found in ripening tomatoes which has been correlated to tomato fruit softening and rotting by numerous investigators in the past. Polygalacturonase was selected as a target for the genetic engineering process of tomato fruit quality improvement based in part on characteristics found in naturally-occurring mutant tomato lines which lack substantial levels of PG activity. Historically, tomato ripening mutants such as the Never Ripe (Nr) and ripening inhibitor (rin) have been used for many years in tomato breeding programs based on certain characteristics determined by these mutations. Two of the most obvious characteristics are very slow softening and extended shelf life. The difficulty with these mutations

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has been that they are pleiotropic in nature, as demonstrated by the fact that genotypes containing these mutations do not evolve ethylene nor do they develop color to any significant degree. These pleiotropic effects have limited the utility of these mutant lines in commercial production.

The antisense approach to eliminating polygalacturonase in tomatoes seeks to avoid the pleiotropic effects associated with ripening mutants and create a product that is more than just an extended firmness tomato, but is a better quality tomato in both fresh market and processing applications. On the fresh market side, this means a tomato that will provide the grower, shipper and packer with reduced spoilage and improved shelf life. It will allow the grower to vine ripen the tomato. It will allow the packer the option of eliminating refrigeration and/or ethylene treatment of the vine-ripened material, enhancing the flavor of the product over the mature green or gassed tomato commonly produced today. On the processing side, inhibiting pectin degradation results in improved field holding of the ripe tomatoes and increased serum viscosity in processed product. Extended field storage will allow the grower to more accurately time the harvest and eliminate waste due to rot. Improved serum viscosity translates into a higher quality processed product.

The antisense approach to regulation of gene expression involves cloning of the gene of interest and transforming that gene into the plant in the reverse orientation. Analysis of mRNA, protein and enzyme activity of transformed plants has confirmed the utility of this approach. Selected transformants have reductions of PG mRNA levels and subsequent enzyme activities of over 99 percent relative to non-transformed controls. Calgene has produced a number of lines of transgenic tomato to test the utility of these new genotypes relative to both the naturally-occurring ripening mutants and non-transgenic controls. To accomplish this evaluation it has been necessary to produce this material on a large scale in the field. This has been accomplished in cooperation with the Campbell Institute for Research and Technology.

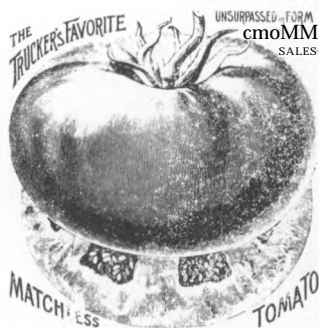
Our first field evaluation was planted in Guasave Sinaloa, Mexico, during the winter of 1988-89. There were several objectives of this trial: morphological evaluation, a test of field holding, and an evaluation of fruit processing characteristics. Morphological evaluation confirmed the lack of any of the commonly observed pleiotropic effects associated with the known ripening mutants. Results of the field holding experiments indicated a significant difference in the ability of the transgenic fruit to hold

up under adverse field conditions, and processing evaluation indicated a highly significant improvement in the serum viscosity and juice consistency of transgenic fruit versus non-transgenic controls.

To confirm these results, as well as make additional selections from numerous transgenic lines, a second field trial was planted during the summer of 1989 in Yolo County, California. Fruit from selected lines was processed for analysis. Results indicated that in all cases, for each non-pectin related parameter measured, (total solids, soluble solids, pH, titratable acidity, and color), there were no differences between transgenic and non-transgenic controls. In the case of the pectin-related parameters examined, very significant positive differences were observed in serum viscosity (Ostwald test). Additional observations made both in the laboratory and in the field indicated the possibility of enhanced resistance of the transgenic material to certain fungal pathogens that are normally encountered both in the field and post-harvest during commercial production. Results of initial laboratory experimentation demonstrated enhanced resistance of transgenic fruit to two common post harvest pathogens, namely *Rhizopus stolonii* and *Geotrichum canadense*. While initial results are encouraging, additional research needs to be carried out to determine the range of enhanced resistance which exists as well as the mechanism involved.

Our most recent field evaluation was conducted in Ruskin, Florida, during the winter of 1990. Material grown included third generation transformation events of three genotypes, CIR1, CIR2, and Rutgers. The focus of this experiment was to evaluate transgenic fresh market tomatoes homozygous for the antisense PG gene for their ability to withstand commercial packing and handling practices at different stages of ripening relative to non-transgenic controls. The trial was planted in February and harvested in late May. Fruit was harvested by hand following standard commercial practices in Florida, sorted depending upon developmental stage (mature green, pink, red) and packed into 25 pound boxes for storage. The finished harvest totaled just over five thousand pounds. Harvested fruit was transported by truck to a commercial packing shed where it was treated as follows: mature green fruit was gassed with ethylene for five days while being stored at 65°F and 65 percent relative humidity and then removed from the gas rooms and stored as described above for an additional five days with the exception of the ethylene gas. Fruit harvested pink and red was stored for ten days as described with no ethylene treatment. After the ten day storage period, the three genotypes, CIR1, CIR2, and Rutgers, were

evaluated for firmness relative to non-transgenic controls by measuring deformation of the fruit under a 500 gram load for a period of 15 seconds. In all, more than 900 fruit were evaluated and the results of the analysis indicate that in all cases, the transformed material was firmer and more intact after ten days of storage as described. Currently, further experimentation is underway to evaluate the utility of this trait in hybrid combination as well as to expand the breeding effort into commercial lines.



## Biotechnologically Modified Animal Products

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The 1990s have become the decade of food safety and environmental awareness. The entire social contract between consumers, food producers and provisioners is in transition. From a consumer's perspective, safety, healthfulness, and the environmental aspects of food are interrelated and inseparable. The dramatic success of agricultural biotechnology has led to expectations and demands for products with desirable composition and food value that are safe and wholesome, and a food supply that is bountiful, appealing, nutritious, healthful, economic, convenient and safe.

In addition, as the American consumer has become more weight-and health-conscious, food is expected to impart health benefits which extend beyond mere nutritive value. Consumers recognize weight gain and its' associated effects on health as a national health problem. The Institute of Food Technologists (IFT) recently estimated that over 34 million people in the United States are overweight—13 percent are described as severely obese. The population has evolved into a "lean conscious society" where a high priority is placed on ways to get and stay trimmer. People are more concerned about exercise, consumers' diet, and food quality assisting in this change in lifestyle. This consciousness is evident in the desire for leaner animal products with less fat and cholesterol than found in traditional animal products.

Along with consumers, the animal industry also wishes to reduce the wasteful production of excessive carcass fat. The current yearly production of six billion pounds of waste and trim fat from beef cattle is equiva-

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**The use of biotechnology will be evident in foods which are modified in composition or character, while technologies used to produce or to assure safety may not be as obvious in the food perse**

lent to two Iowa corn crops in feed energy, and must be reduced as rapidly as possible. While extensive trimming of animal products' fat occurs from slaughter through to the consumer and results in a reasonably lean animal product, preventing excessive fat deposition where it occurs will minimize carcass waste, increase production efficiency, and effectively reduce the caloric content of the animal product delivered to consumers.

To accomplish this requires use of biotechnology in the production segments; for animals this is during stages of growth and production. A rapidly increasing fraction of consumers also expects foods to be further processed and table or consumption ready, requiring new technologies in post-harvest segments of food production. Further, the desire for food safety assurance will require development and integration of sensitive biotechnology-based monitoring throughout all stages of producing a food from conception to consumption in HACCP quality assurance systems.

### **Role of Biotechnology in Quality and Safety of Animal Foods**

The use of biotechnology will be evident in foods which are modified in composition or character, while technologies used to produce or to assure safety may not be as obvious in the food ytr si. Nonetheless, all are important in economically producing consumer-desired products. Perhaps, in part, because such a small fraction of the United States population (i.e., less than three percent) is directly involved in production agriculture, time and opportunities exist to surface concerns regarding the way in which foods are produced.

Consumers, for several reasons, have become increasingly concerned about the quality and safety of the food supply, including animal derived foods. This reflects concerns surfaced through media and special interest attention to unknown risks in the environment and food supply. Consumers are now questioning whether, in fact, biotechnology should even be used in food production. The basis for biotechnology's use in producing consumer-desired animal products must be explored in order to further understand these concerns.

### **Why Use Biotechnology in Animal Production?**

The animal industry must regulate animal production in order to deliver consumer-desired foods and/or other required specialty (i.e., health) products. Appropriate technologies allow the modification of animal products

to better fit consumers' nutritional needs and desires. Currently it is difficult sometimes to separate food from medicine since many foods contain components (i.e., specific types of fibers) associated with improvement in some body function. As opportunities arise to genetically engineer animal systems to produce specific needed protein compounds, such as insulin and other life-support proteins in milk, the distinction between medicine and food will become even more clouded. Biotechnology will become an even more important component in the modification or regulation of key aspects of animal production from conception of the animal through delivery to the consumer, to allow the efficient provisioning of needed animal-based food and health products.

Current technologies used in animal production modify growth, resulting in leaner products with less fat. For example, beef production incorporates anabolic implants which produce a leaner product. Emerging technologies promise similar options for pork and poultry, with applications for fish as well. It would be unfortunate if safe, efficacious technologies for producing safer and healthier consumer-desired animal products were rejected by consumers on the basis of misinformation through special interest (i.e., vegetarian, animal rights) agendas. In assessing options for the use of biotechnologies, those which enhance real and/or perceived product quality or safety and the quality of life of the consumer are most readily accepted. Unfortunately, the value of these technologies has not been communicated to consumers with the same message penetration as the emotional appeal for "natural" food production systems.

### **What Needs To Be Modified In Animal Food Products?**

Food products suitable for biotechnological modification include meat, milk, and eggs. Many animal products currently produced may need to be modified to provide foods more closely aligned with contemporary nutrient needs and food choices of specific consumers. For many reasons, amounts of fat, specifically those fatty acids known to elevate cholesterol production (saturated with more than 16 carbons) or those known to enhance tumor growth (i.e., 18:2, linoleic), may need to be reduced in common diets in many people. Hence, appropriate changes in both fat content of foods and composition of fat present (fatty acids) may be desirable. Cholesterol levels in foods per se are not as important, because only a small fraction of this cholesterol is absorbed—therefore diet contributes only a very small fraction of the overall daily cholesterol production in humans. Nevertheless, consumer perceptions indicate that a reduction in cholesterol levels in animal foods would also be desirable.

Other modifications could also be useful. For example, the amount and type of protein present in foods is also important, and changes in animal function to produce consumer-desired types of protein (e.g., white vs. red meat, fiber size, etc.) would be useful. Biotechnology which reduces levels of natural carcinogens, or enhances levels of anti-carcinogens also would be important in producing animal foods which are perceived as safe. Options to accomplish this currently exist for some components (e.g., aflatoxins) and have been studied or are in development for others (e.g., pesticides).

### **Mechanisms To Modify Animal Products**

Animal food products represent an integration of events ranging from initiation to harvest, and from post-harvest processing to produce, preserve and deliver foods to consumers. In turn, biotechnological options to modify animal products exist in all segments of production. Some key options include: modification of substrates used, modification of growth and systemic production processes, and post-harvest product processing. These are accomplished in several ways and can be categorized as follows:

- feedstuff selection and processing
- digestive tract processing physiology
- physiological repartitioning
- tissue specific modification

**Feedstuff Selection and Processing** Although this is an area that has received substantial attention, especially in recent years, feedstuff selection and processing is not a new phenomena. For quite some time, mechanisms which modify the fatty acid composition of animal products have been established, particularly in animals, with minimal microbial modification of feeds prior to absorption. For example, the fatty acid composition of pork and poultry products largely reflects dietary fatty acid composition. As a consequence, composition of fat within some limits can be modified easily in meat products from these species through the selection of feed ingredients.

Once a desirable combination of fatty acids for human needs is clearly established, feeding-management systems can be developed to produce products which better reflect these needs. Challenges in the preservation and development of consumer-acceptable products with modified fatty acid composition are substantial and will provide numerous opportunities for biotechnology.



Further opportunities to modify the fatty acid composition of products such as meat and milk from cattle and sheep are limited currently and will

**Another area of biotechnologically important feedstuff processing is the development of procedures to sequester, degrade and/or limit absorption of natural and synthetic toxins such that safer animal products without these toxins can be produced consistently.**

require development of novel biotechnology to make substantial progress. Selection and processing of feedstuffs to limit microbial access to, and modification of, fatty acids represents an area of current interest and considerable challenge. Some progress with calcium and other salts of fatty acids (i.e., fatty acid soaps) has been demonstrated and products are currently being marketed for dairy cattle, primarily to increase energy intake and milk fat production with lesser emphasis on modification of milk fat composition. Further development of related biotechnology will be required to produce significant modification of fatty acid composition of beef or lamb products.

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Another area of biotechnologically important feedstuff processing is the development of procedures to sequester, degrade and/or limit absorption of natural and synthetic toxins such that safer animal products without these toxins can be produced consistently. For example, products developed for other feed uses have found application in binding aflatoxins to limit absorption in animals, thus reducing levels of toxins in products such as milk. Further development of this technology is encouraged, emphasizing options which limit further transfer of natural, environmental, crop production and microbial feedstuff toxins to animal products. Such measures will be required to establish consumer confidence in the production of safe meat and milk products.

**Digestive Tract Processing Physiology** Much research has been conducted on digestive physiology in order to understand the absorption mechanisms for various nutrients and substrates for metabolism. Biotechnological applications in two major areas may be important. One, options which alter the distribution or function of specific microbes in the fermentative compartments of the digestive tract of ruminants may in turn alter the substrates delivered for use to the animal tissues. Possible modifications include: volatile fatty acids and long chain fatty acid modification and synthesis resulting in altered composition of fat in animal food products produced. Two, modification of the digestive tract conditions and processing through pH, enzyme activity, flow rates, passage, retention time, and absorptive mechanisms, among others, will allow altered substrate

**The objective is to repartition the growth patterns in animals to produce a leaner animal product and less fat from all animals.**

delivery to the animal tissues. This will modify the rate and composition of animal tissue growth, producing modified food products.

#### Physiological Repartitioning to Produce Leaner

Animal Products Repartitioning of growth and the consequent modification of animal products has received major attention in recent years. Repartitioning clearly provides the most direct and efficacious mechanism for changing the protein and fat content of animal tissues. The objective is to repartition the growth patterns in animals to produce leaner animal products and less fat from all animals. While repartitioning is the eventual goal of many genetic engineering initiatives, systems employing these concepts such as transgenic animals are not likely to surface any time soon. A number of options are feasible in developing systems employing growth regulating biotechnology in several forms to produce leaner animal products, and these include the following:

- a. Genetics
- b. Endogenous regulation
  - intact animals
  - castrated-spayed
  - autoimmunization
- c. Exogenous regulation
  - repartitioning agents
  - estrogens
  - zeranol
  - androgens (e.g., TBA)
  - growth hormone
  - beta-agonists
  - growth hormone releasing factor

Mechanisms of regulation include: priorities for protein vs. fat, redirection of nutrients, tissue mobilization, and limits for daily deposition

All options listed above have been investigated to varying degrees across animal species in developing targeted growth management systems to most efficiently produce desired leaner animal products. While genetic directives provide general targets for body and carcass composition, other factors really determine the extent to which these theoretical limits will actually be reached, or how patterns and priorities for growth will be followed or translated into and realized as growth. In all animal types, the energy available translates genetic directives through tissue regulation into patterns of growth.

Nutrition is directly linked to rate and composition of growth in several ways. Available energy is used to meet maintenance needs, protein growth, and fat deposition, primarily in that order. Thus, composition of meat products reflects levels of available substrates provided relative to maintenance and limits for protein growth with additional energy usually deposited as fat. The magnitude of nutritionally regulated changes in body composition at a given weight reflect animal priorities, rates of growth and length of time that animals are growing at respective rates. Slower (deferred) growth for extended periods of time invariably results in leaner carcasses at any selected weight. External regulation through growth-regulating biotechnology redirecting growth allows the integration of growth potential with nutrient supply resulting in the desired animal products.

Repartitioning mechanisms involved in redirection of growth include: modification of priorities for nutrient use for protein vs. fat deposition; alteration of tissue turnover; modification of daily tissue deposition limits; and modification of nutrient supply. Eventually, growth hormone, releasing factors for growth hormone, beta-agonists and/or immunization strategies to remove negative feedback on growth (e.g., somatostatin) may provide additional mechanisms with which to regulate growth. These may work in concert with, or replace, current growth regulation technology. These alternatives are currently in development.

Current estrogenic growth regulators such as growth hormone, and beta-agonists used in development for several animal species, are effective repartitioning agents which modify growth by shifting nutrients from fat to protein accretion (Fig. 1). Also they usually enhance rate of growth as well, serving to further increase lean tissue production. Rate and efficiency of lean tissue growth are critical components in enhancing lean animal production through conventional animal feeding and management systems. In addition to more efficient production, they provide the opportunity to regulate growth in order to tailor animal production to meet consumer desires for leaner animal products. While current growth regulators have been used for several decades, the basis for their function has only recently begun to be understood. This understanding is important for the development of growth regulation systems which allow programmed growth of animals.

Recent research provides new insights into the mechanisms by which growth regulating biotechnologies operate in animals. Protein growth is a daily function, and theoretically, cellular mechanisms establish the maxi-

mal rates for daily protein synthesis. In actuality, cellular limits for protein growth are not often reached due to physiological factors, including hormonal and nutritional mechanisms which set priorities limiting protein deposition.

While several options exist for producing leaner animal products, the product must be acceptable, even desirable in the marketplace. Thus, the degree to which these production strategies impact the production of lean animal products must also be assessed in terms of product acceptability. For example, forage-fed beef, because of its darker and softer lean will not have the retail case shelf-life equal to that of grain fed beef. This presents a serious problem from the consumer acceptance standpoint. Meat from these carcasses is also borderline in taste acceptability. Tissue Specific Modification Growth regulators and repartitioning agents function through reducing fat deposition. Since a relationship of fatness to marbling exists, a reduction in marbling and resulting quality

grade can be expected when fatness is reduced. However, for example, with current estrogenic growth regulators, consumer acceptability, shear force, palatability and tenderness are altered to a lesser extent than expected from the reduction in fat. This reflects the greater reduction in subcutaneous and kidney-pelvic fat than in intramuscular or marbling fat with estrogenic growth regulators when nutrients are redirected from fat to lean. This allows carcass quality to be maintained with a lower total degree of fatness.

### **Safety Background**

Growth regulators currently approved for use with beef cattle are either endogenous compounds already present in human and animals (e.g., estrogen, testosterone, or progesterone), or are compounds developed through biotechnology to mimic these endogenous substances (e.g., zeranol or trenbolone acetate). None of these compounds are ever fed to animals in the United States. Instead, they are placed in the ear, which does not normally enter the food chain. When used in cattle, production residues in meat are extremely low and lower than naturally occurring levels in meat from cows and bulls. Levels of hormones produced in people every day are many thousands to millions times greater than present in meat either naturally or as a result of use of a growth regulator in cattle. Also, other foods, especially vegetables, salad oil, etc. provide thousands of times more estrogen than meat from cattle, whether receiving growth regulators or not, and less than 10 percent of what is consumed is absorbed by humans—so the contribution from beef is truly negligible.

Growth regulators in development, including growth hormone, beta-agonists, growth hormone releasing factor, and immunization will be equally safe but also subject to public perception.

### **European Economic Community Safety Issues**

The European Economic Community (EEC) imposed a ban on beef imports from the United States and other countries using anabolic growth regulators commonly referred to as “hormones”. The ban was originally launched under the guise of “safety” issues. The directive for the ban has been adopted by the EEC although all safety issues were dismissed long ago by both the EEC's own commission, “The Lamming Commission” and by the United States own regulatory agencies, the Food Safety and Inspection Service (FSIS) branch of USDA, and FDA).

**While the need to produce leaner, health-promoting animal products has become painfully clear, the segmentation of the industry, and its' divergent goals, objectives and profit centers, has resulted in mixed signals at best.**

In contrast to the United States, where biotechnology is tightly and efficiently regulated such that no violative residues were found in the past four years of the USDA-FSIS National Residue Program, as much as one fourth of the beef produced in the EEC contains unacceptable residues of compounds never cleared for use in cattle. Some of these compounds are known carcinogens such as DES. A safety issue exists with EEC beef because of the use of unapproved "cocktails" of many potent drugs directly injected into the muscle of growing cattle on EEC farms which came about as a result of bans on the use of approved products instated during the past two years.

### **Current Market Signals**

While the need to produce leaner, health-promoting animal products has become painfully clear, the segmentation of the industry, and its' divergent goals, objectives and profit centers, has resulted in mixed signals at best. In typical scenarios, incentives to produce fatter animal products often prevail. Incentives for producing leaner animal products must be established in all segments of the industry to assure coordination of growth toward optimal market endpoints.

One of the major problems is the short "shelf-life" of animals nearing slaughter endpoints. The concept of shelf life was developed to define the time and/or weight interval over which an animal maintains its current quality or yield grade. For some animal types, shelf-life in the feedlot may not be appreciably longer than post-harvest shelf-life in the retail trade. Extending this interval would provide more flexibility in marketing, and animals could increase in fatness at a slower rate, so that overfeeding would be less deleterious to lean animal production. Repartitioning agents provide options for increasing the shelf life of animals.

### **Diet-Health Aspects of Modified Animal Products**

In concert with consumer desires to be, think, and eat "leaner", there is also an interest in reducing fat consumption, particularly saturated fat, and cholesterol levels—both dietary and circulating. The most common concerns are that animal products are high in calories, saturated fat, and cholesterol.

An average three-ounce cooked lean beef, for example, provides only 73 mg of cholesterol, which is less than 25 percent of the American Heart Association's recommendation of 300 mg per day. This average three ounce

portion of cooked lean beef provides only 192 kcalories of energy, less than 10 percent of a 2000 kcalorie diet. Less than half of this energy (85 kilocalories) comes from fat and the saturated fat component contributes only half of that. These levels of calories from fat are far below the American Heart Association's recommendations of no more than 30 and 10 percent of total calories from fat and saturated fat, respectively. As is evident, lean animal products fit well within dietary guidelines; the challenge from the production perspective is to produce inherently lean animal products which do not require extensive trimming along the retail chain. Opportunities for reduction in fat and fatty acid modification will further advance the potential to deliver consumer-tailored, safe and healthful animal products.

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### **Implications of Social/Political Policy**

Recently, the EEC proposed a ban on imports of animal products from countries using growth regulators. Recent data were summarized to assess the impact on the industry in the United States. In a summary of growth regulation studies at Texas A&M University, the change in net return on a lean retail product basis including feed, interest, implant cost, yardage and with an average retail product value of \$2.50/lb, averaged \$96.68 per animal. This represents a net value to the United States beef industry of approximately 2.5 billion dollars with these data as above. These data are consistent with results of a 1987 USDA study indicating a \$2.4 to \$4.1 billion reduction in net return on a retail products basis if currently approved growth regulators were not used in the United States depending on feeding and marketing management alternatives. Worldwide implications would obviously be much greater, and this is borne out in the USDA study.

Clearly, when safe, approved, efficacious biotechnology is banned to serve popular, protectionist, or political purposes, only unapproved technology will be available for use. Use of approved safe growth regulators allows application of biotechnology to produce leaner beef products consistent with dietary and health needs of consumers. The ban on this technology in the EEC has resulted in the delivery of fatter beef products to European consumers, a situation inconsistent with the needs of United States and other consumers.

Similar restrictions are forthcoming or are currently in place regarding the use of growth hormone-based technology currently in development to modify meat animal products (i.e., EEC) or quantity of milk produced per animal (as seen in Minnesota and Wisconsin).

In producing environmentally sensitive animal products, the adoption of technology (such as grain feeding, ionophores) to reduce methane, or growth regulators to enhance lean tissue growth, reduces the methane per unit of beef produced. Elimination of these technologies (i.e., growth regulation ban by EEC) would result in decreases in rates of lean tissue growth and more methane per unit of beef produced. Hence, disallowing technology for more efficient production of meat (growth regulators by EEC) or as suggested for milk production (i.e., BST) would directly increase the animal contribution to global warming by requiring the production of more methane per unit of product, be it meat, milk, fiber or draft power. While the contribution of the United States beef cattle industry to annual global methane production (0.5 percent of total estimated production, 0.1 percent of all global warming) is not outstanding, it will be important to facilitate transfer of all available technology to enhance rate and efficiency of growth to reduce methane emissions from beef cattle production systems in the United States and worldwide, to further limit the contribution of cattle to global warming and changing of the earth's climates.

## Conclusions

Meeting the demands imposed by consumers and industry for health consciousness and animal efficiency in the production of high quality, safe, lean, and healthful animal products requires immediate attention to the issue of increasing lean tissue and reducing fat deposition in animals. The ability to produce highly palatable and acceptable lean animal products is of critical importance for the animal industry. The calorie consciousness of consumers requires a sincere effort on the part of the animal products industry to produce leaner animal products to meet diet and health concerns of an increasingly perceptive consumer. Lean animal products fit well within dietary guidelines; the challenge is to produce animal products that are lean in the carcass and do not need extensive trimming along the retail chain to make them lean.

Unique challenges face the animal industry in the design and development of new technologies that will allow production of lean animal products rather than require extensive trimming to make them lean. This will require development of greater lean tissue deposition throughout the life cycle and extensive redirection of feed energy from fat to protein growth through all phases of growth.

However, society is increasingly concerned about the use of chemicals and residues in our food supply. The animal industry must develop, communicate and extend the use of current and new biotechnologies and sys-



tem to efficiently produce leaner animal products. Technologies providing economic return without known benefit in enhancing quality of life and/or with perceived negative human health implications (e.g., residues) may be short-lived.

Our primary challenge is to develop systems employing current and new biotechnologies which will allow us to produce specific uniform products from diverse animal production systems in a range of designer foods.

**The successful development and implementation of animal products will depend on consumer desires and demands.**

Most importantly, we must clearly 1) define needed consumer attributes of specific products and then 2) derive targeted-integrated biotechnology based production systems to efficiently produce these products in order to 3) develop more desirable products than currently exist in the animal products industry. Our total system from conception to consumption must be consumer driven and must focus on the final target

product as biotechnology-production-management-marketing options are selected. Concurrently, all technology implemented in the production system must eventually be marketed to the final consumer as well; currently this is seldom accomplished. There will be increasingly limited opportunities to use technologies inconsistent with quality of life of consumers, and in the future, both the product as well as the system used to produce it will need to be consistent with consumer needs and attitudes.

The successful development and implementation of animal products will depend on consumer desires and demands. While animal-product biotechnologies have the potential to provide seemingly desirable products more efficiently than current systems, their introduction and development relies ultimately on consumer acceptance. In addition to consumer concerns, consumers and developers alike need to consider carefully the social and economic implications of biotechnological developments.

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## Food Processing Biotechnology

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The food chain can be viewed as a continuum from the planted seed to the processing, distribution and marketing of products, to the consumer's table. The food processing industry serves as the vital link between the farmer and the supermarket. Except for fruits and vegetables that are often consumed raw, most agricultural products undergo some kind of processing after leaving the farm gate. Biotechnology can obviously be used to improve the safety and nutritional quality of the food supply at every link in the chain. Previous examples have focused on how it can be used to improve the production end of the food chain. Any genetic improvement in plants and animals that serve as raw materials for processed foods will impact the processing of that product; therefore, processing parameters are an essential element of any strain improvement strategy. However, the following discussion will focus on how biotechnology can be used to improve the processing of food — the utilization end of the food chain — from the time the raw product leaves the farm gate until it is consumed.

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A stroll through a modern supermarket vividly illustrates how processed foods have changed in the last 10 years. With increased consumer awareness and concern about food quality, safety, nutrition, and convenience, the food processing industry has responded by formulating and marketing products that meet consumer demands and expectations. It is common to see expanded refrigerated and frozen food sections, a wide variety of fresh fruits and vegetables, extensive delicatessen sections featuring partially processed foods, and a vast array of microwavable products. New product develop-

ment often requires the utilization of new processing, preservation, packaging and distribution systems, and these new systems may create the potential for new microbiological, safety, quality or nutritional concerns. For example, although modified atmosphere or controlled atmosphere packaging (MAP/CAP) and vacuum packaging can be used to improve quality and extend shelf-life of minimally processed refrigerated products, it also creates an environment that could permit the growth of deadly pathogens. Restricted use of nitrate in bacon or sulfite in potato processing creates similar microbiological safety concerns. Microwave ovens have revolutionized home food preparation, yet uneven heating could create microenvironments that allow survival of pathogenic organisms. To meet consumer demands and at the same time ensure food quality and safety will require application of innovative and effective technologies, including biotechnology-

### **What is Biotechnology?**

Biotechnology has been defined as a collection of technologies that use living systems (plants, animals, or microorganisms), or compounds derived from living organisms, for the production of industrial goods and services (Office of Technology Assessment, 1981). Biotechnology is not new to the food processing industry as humans have been exploiting living systems for the production, processing and preservation of food for centuries. Mutation and selection techniques have been used to improve strains of bacteria and yeast used to produce fermented foods, such as cheese, sausage, bread and wine. Many ingredients used in processed foods including vitamins, stabilizers, enzymes, flavor enhancers and preservatives are currently produced by bacteria. What distinguishes the more traditional "old" biotechnology from the "new" biotechnology is the emergence within the last 20 years of genetic engineering that allows the exchange of genetic information between related and unrelated organisms. Other molecular biology techniques, including hybridoma technology, DNA probe technology, enzyme and protein engineering, bioengineering and fermentation technology, and plant and mammalian cell culture, are also included under the umbrella of biotechnology.

### **Applications of Biotechnology to Food Processing**

Genetic improvement of food fermentation microorganisms Bacteria, yeasts and molds have been used for the production of fermented foods for thousands of years. Classical strain improvement methods involving muta-

tion and selection are imprecise and uncontrollable, it is impossible to screen for all mutations that might occur, and the screening process is laborious and time consuming. In addition, one is limited to the genetic information already present in the organism. Genetic engineering provides a mechanism for overcoming many of these limitations as it allows for the selection and transfer of single, well-defined traits from virtually any living organism in a precise, controllable and predictable manner. Table 1 illustrates how genetic engineering can be used to improve microorganisms used in food fermentations. Examples include the impact of genetic improvements on the processing, nutritional value, microbiological safety and shelf-life of fermented foods.

Table 1 Genetic improvement of food-grade microorganisms

Type of Nature of Fermentation Improvement Implications		
DAIRY		
Cheese	Bacteriophage (virus) resistance	Eliminate economic losses due to destruction of culture by viruses
Yogurt	Accelerated ripening	Decreased storage costs
	Higher levels of betagalactosidase	More digestible product for lactose-intolerant individuals
MEAT		
Sausage	Bacteriocin production	Inhibition of pathogens and spoilage organisms
CEREAL		
Beer	Alpha-amylase production	Used for production of "lite" or low calorie beer
Bread	Higher levels of maltose permease and maltase	More consistent and improved leavening

(Taken from Harlander, 1989)

It is important to note that the first genetically engineered food-grade microorganism was approved for use by the British Ministry of Agriculture, Fisheries and Food on March 1,1990. The manufacturer, Gistbrocades, was granted permission to manufacture and supply the particular strain of yeast, *Saccharomyces cerevisiae* 352 Ng, used in the baking industry. The strain was genetically engineered to produce elevated levels of two enzymes involved in starch utilization, maltose permease and maltase. Consistent fermentations result in doughs containing widely different sugar concentrations thus ensuring product quality.

**Healthy microbes** Over 70 percent of the world's population lose the ability to ferment lactose due to the gradual loss of lactase, an enzyme present in the brush border of the intestine that hydrolyzes lactose into glucose and galactose. Several investigators have demonstrated that lactase-deficient individuals digest lactose from yogurt much more efficiently than lactose from other dairy foods (Savaia and Levitt, 1987). Genetic engineering could be used to enhance the level of microbial  $\beta$ -galactosidase produced by *Streptococcus thermophilus* and *Lactobacillus bulgaricus*, the two organisms used in the manufacture of yogurt, making the product more easily digested by lactoseintolerant individuals. Because elderly individuals frequently experience difficulty in digesting certain food products, it may be possible to use yogurt culture as delivery systems for other digestive enzymes for certain target populations.

**Probiotics** Numerous strains of bacteria are capable of implanting and competing in the gastrointestinal tract of humans and animals. These organisms are often classified as "probiotic" as their function is to aid the host in some beneficial manner. Construction of strains capable of competitively inhibiting potentially pathogenic gut organisms could have several applications in agriculture and food. For example, nonpathogenic strains of *Salmonella* or other gut organisms could be engineered to produce broad spectrum bacteriocins. These strains could be supplied in poultry feed and water for biological control of pathogenic strains of *Salmonella* or other gut pathogens. The same concept could be applied to other animal species and to humans, as well. *Lactobacillus acidophilus*, a food-grade microorganism used in the production of acidophilus milk, is capable of surviving passage through the stomach, and under certain circumstances is able to colonize the GI tract. It may be possible to engineer bacteriocin-producing strains with enhanced colonization capability could be used to modulate the ecology of the gut. Consumption of products containing these engineered strains could be recommended for individuals who have completed antibiotic therapy, for travelers who might be exposed to food-borne pathogens, or for immunocompromised individuals who are susceptible to endemic diarrhea or yeast infections.

**Microbiallyderived ingredients** Microorganisms produce a host of metabolites currently used as ingredients in processed food products (Neidleman, 1990). These include acidulants (acetic, lactic, benzoic, propionic), flavors (diacetyl, pyrazines, lactones, esters), flavor enhancers (MSG), pigments (monascin, astaxanthin), stabilizers and thickeners

(xanthan gum, dextrans), nutritive additives (vitamins, amino acids), sweeteners (aspartame), enzymes (proteases, lipases, cellulases, pectinases) and preservatives (nisin). These ingredients add functionality, enhance nutritional quality, extend shelf-life, improve convenience and ensure safety.

Many of the ingredients listed above are produced by organisms that have a long history of safe use in foods. However, there are many microbes in nature that produce interesting compounds that could be used in processed foods. For example, many bacteria produce extracellular biopolymers that could be used as stabilizing agents, viscosifiers, surfactants, flavor encapsulating agents, noncaloric gelling agents, and as a source of soluble fiber in the diet. There is tremendous interest in transferring the gene(s) that code for production of these biopolymers into food-grade microorganisms.

Enzymes Enzymes are used extensively by the food industry as processing aids to control texture, appearance, flavor development, and nutritive value of processed foods. For example, various proteases are used to tenderize meat, pectinases are used to decloud fruit juices, amylases are used to degrade starches, caffeinases are used to decaffeinate coffee, and oxidases are used to remove off flavors (Neidleman, 1986).

**Approval of this enzyme is a significant milestone for the food industry as it establishes a critical regulatory precedent and serves as a model for other biotechnologically-derived enzymes and ingredients.**

An historic event for food biotechnology was the recent affirmation (March 23, 1990) by the Food and Drug Administration (FDA) of "generally regarded as safe" (GRAS) status for the first recombinant enzyme to be used directly in food. Recombinant chymosin or rennet is an enzyme that is used to accelerate curd formation during cheese manufacture. Recombinant rennet is produced by a genetically engineered strain of *Escherichia coli* and is purified from the fermentation broth. It is interesting to note that the plasmid vector codes for an antibiotic resistance marker and

that the producing strain, although not pathogenic in nature, is a gut organism that did not enjoy a long history of safe use in food prior to this application, yet achieved FDA approval. Approval of this enzyme is a significant milestone for the food industry as it establishes a critical regulatory precedent and serves as a model for other biotechnologically-derived enzymes and ingredients. It is also interesting to note that the recombinant product contains more active enzyme per unit protein and is microbiologically safer than the traditional counterpart which is extracted from the forestomach of calves.

**Enzyme engineering** Most enzymes function optimally at physiologic temperature and pH; this is not the conditions encountered in food processing operations that frequently involve high temperature and low pH. Genetic engineering techniques (site-specific mutagenesis) have been used to specifically alter the primary amino acid sequence of enzymes to improve their functionality in food systems. Some examples of how enzyme engineering could be used to improve enzymes used in food processing are provided in Table 2.

Table 2  
Suggestions for improved enzymatic activity through enzyme engineering

Enzyme	Application	Useful Improvement
alpha-amylase	Starch liquefaction	Acid-tolerant and thermostable
amyloglucosidase	High fructose corn syrup production	Immobilized with higher productivity
esterases, lipases, proteases, etc.	Flavor development	Improved substrate specificity
glucose isomerase	High fructose corn syrup production	Increased thermostability
limoninase	Debittering of fruit juices	More complete limonin degradation
protease	Beer chill proofing	Improved substrate specificity
pullulanase	High fructose corn syrup production	Increased thermostability

(Taken from Neidلمان, 1986)

**More Efficient Utilization of Raw Materials**

Environmental concerns and economic issues necessitate better utilization of raw materials and reduction of waste generated by the food processing industry. In the past, food processing waste streams were discharged into the environment or buried in landfills. However, the bioburden is great and soil microorganisms are not capable of degrading compounds at a fast enough rate. Whey from cheese manufacture, cellulosic waste from vegetable processing, shells from nut processing, and starch from potato processing are but a few examples of the kinds of waste streams generated by the food industry. More innovative methods for converting these materials to valueadded products must be developed. In other countries, food processing waste streams are used as feedstock for subsequent fermentation



**As our supply of petroleum-based chemicals are depleted, biotechnology-based methods will be needed to more efficiently utilize waste streams, surplus commodities and other renewable agriculture resources.**

processes used to produce food and nonfood products including pharmaceuticals and specialty chemicals.

As our supply of petroleum-based chemicals are depleted, biotechnology-based methods will be needed to more efficiently utilize waste streams, surplus commodities and other renewable agriculture resources.

### **Food Safety**

Although it is generally agreed that the U.S. enjoys the safest food supply in the world, emerging pathogens, not previously associated with food, have been responsible for recent outbreaks of food-borne illness. Within the last five years, the dairy industry has had to cope with the emergence of the pathogenic organism, *Listeria monocytogenes*, which is capable of causing spontaneous abortion in pregnant women, and meningitis in infants, the elderly, and immunocompromised individuals. A strain of *Salmonella enteritidis* has been isolated from intact eggs and entire flocks of poultry appear to be endemically infected with the organism. There is also increasing consumer concern about microbial toxins, aflatoxin, chemical residues (herbicides, pesticides, fertilizers and fungicides), antibiotics, and animal drug residues in raw and processed foods. Rapid and sensitive methods based on the development of DNA probes and polyclonal and monoclonal antibodies could revolutionize quality control and quality assurance in the food industry. Theoretically, these tests should be capable of detecting a single organism or toxin molecule, thus dramatically increasing the sensitivity over current methods. In addition, test results are available in hours or days rather than weeks or months.

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### **Biosensors**

The highly specific action of enzymes and microbial cells can be exploited as analytical tools to measure the concentration of specific components in complex mixtures. Enzymes, antibodies or whole cells can be immobilized onto solid surfaces, and the specific reactions they mediate can be detected electrochemically, photometrically, thermometrically or mechanically (Wagner and Schmid, 1990). In food systems, biosensors can be used to measure low molecular weight, single compounds such as glucose, organic acids, amino acids, alcohols or food additives; complex compounds such as microorganisms and biological or chemical contaminants; and complex quality parameters such as freshness, shelf-life prediction, flavor, maturity

or thermal stress. Some examples of biosensors currently under development are listed in Table 3.

**Table 3** Commercially available biosensors for food analysis

Analyte	Biocomponent	Application
Glucose	Whole bacterial cells Glucose oxidase enzyme	Molasses production Brewing, various fermentations, fruit juice and soft drink manu- facture, banana maturation
Lactose	P-galactosidase enzyme	Raw milk
Sucrose	Invertase enzyme	Instant cocoa manufacture
Lactate	Lactate dehydrogenase enzyme	Dairy products, yogurt, whey
Ethanol	Alcohol dehydrogenase enzyme	Alcoholic beverages, wine, beer, cider, fermentations
Peptides	Amino peptidase enzyme	Casein hydrolysis
Amino acids	Amino acid dehydrogenase enzyme	Many foods
Glutamate	L-glutamate oxidase enzyme	Soy sauce manufacture
Aspartame	L-aspartase enzyme or alcohol oxidase enzyme	Level of sweetener in many foods including soft drinks
Ascorbic acid	Ascorbate oxidase enzyme	Fruit juices
Sulfite	Sulfite oxidase enzyme	Dry fruit, wine, vinegar, juices, potato flakes
Penicillin	Antibody-enzyme conjugate	Milk
PHB ester	phydroxybenxoate hydroxylase enzyme	Fruit juices and drinks

Taken from Wagner and Schmid, 1990).

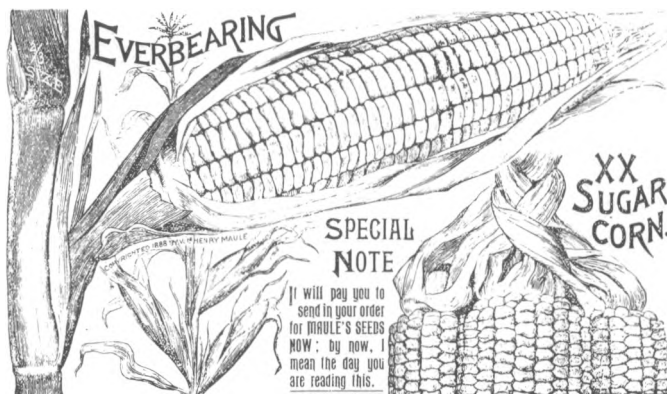
## Conclusions

Biotechnology could have a dramatic impact on the entire agriculture and food sector. It has the potential to reduce the need for agricultural chemicals; improve the productivity, efficiency, and profitability of food production and processing; open new markets for improved or unique processed food products; and, improve the nutritional quality, safety, cost, and convenience of consumer food products. Any improvement of the food supply at any point in the food chain will ultimately impact the utilization end of the system and the ultimate beneficiary of the improvement — the consumer.

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## Government Regulation: Insuring Safety and Quality \*\*

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This paper provides a brief outline of the regulation of biotechnology across the board in the United States today. An important feature of this discussion is that its focus is not on laws and regulations for the issues of biotechnology, but rather on science.

It is no surprise to those who work in this legislative area that regulation is not driven by legislators, lawyers and regulators, but that it is driven by the science that underlies the regulation. The history of government regulation of the food supply is the history of science, not the history of the laws and regulations that have been involved.

This is illustrated by the following example from a statute enacted by the English Parliament in 1263. Parliament decreed, in order to protect the safety of the food supply, that nothing could be added to the then staple foods in England that was "not wholesome for man's body". The statutory standard today is remarkably similar, stating that nothing can be added to foods if it is a "poisonous or deleterious substance that may render the food injurious to health". And I challenge anyone to point out the difference between "not wholesome for man's body" which was the statutory standard 700 years ago, and "poisonous or deleterious substance which may render the food injurious to health", which is our statutory standard today and has been since the English statute of 1860. There is no difference.

If the 1263 law was the only law of the land today, the Food and Drug Administration (FDA) and United States Department of Agriculture (USDA) would be

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**The history of government regulation of the food supply is the history of science, not the history of the laws and regulations that have been involved.**

doing nothing differently. Thus the issue is clearly an issue of science, not of laws and regulation.

Government regulation of food and drugs, (which have always been related), has been of concern in our country for its entire 200 year history. Our earliest governmental federal statutes regulating any form of business were directed at the drug supply. From the

Vaccine Act of 1813 on through the latter part of that century there was a plethora of laws and regulations enacted to prevent importation and exportation of adulterated food of any kind. These laws and regulations did not deal with regulation of domestic commerce of food and drugs because of a concern that these were matters for state and local governments only.

In the last quarter of the 1800s in the United States we had a constitutional debate in Congress, in particular, over the role of the Federal Government which at that time was thought to be restricted to foreign commerce. Domestic commerce was considered a matter solely for state, local and county governments.

It was only the first decade of this century that Congress' and the Supreme Court's view changed. At that time, the laws that are seen today were put in place. Between 1900 and 1910, there was the Vaccine Act of 1902, the Food and Drugs Act of 1906, the Federal Meat Inspection Acts of 1906 and 1907, and the Insecticides Act of 1910. These laws effected what we still regard, with years and decades of enactment and revision, as our basic food protection laws. In the 1970s a plethora of amendments and revisions and new environmental statutes were added. In addition to these regulatory laws, an overlay of broad statutory authority exists, vested in the United States Government, which regulates indirectly.

For example, the National Institutes of Health (NIH), the Department of Defense and other government agencies have broadly contracted grant authority, and that authority can be used to impose any form of restriction believed reasonable. That was the origin of the recombinant DNA guidelines created in the 1970s at NIH.

Many basic research scientists in the debate that occurred in the mid-1970s were shocked to discover that they could be regulated. The theory was promoted in conferences such as this from 1976 to 1978, by scientist upon scientist who took the lectern and said, "We demand the right to freedom of speech!", to which I always responded "Everybody in this country has the right to freedom of speech, but you do not have the right to free-

Scientists are as subject to regulation in our country as any other form of commercial enterprise. means potentially putting others at danger." Our courts have always been quick to point out the difference between speech and action. Any research scientist who wished to espouse recombinant DNA re-

search was free to do so without restrictions. But once in action, the basic bench scientist stands in no different a position than the railroad or the pharmaceutical industry, or the food industry or anybody else. Scientists are as subject to regulation in our country as any other form of commercial enterprise. I cannot tell you how disappointed the research scientists were to hear that news.

Regulatory statutes can often be divided into two basic kinds of statutes—those that deal with products, like foods and drugs, and those that deal with processes, usually industrial processes, like clean air and clean water.

For the purposes of looking at how recombinant DNA and biotechnology can be regulated, it is presented as a progression from the laboratory to the consumer. This progression begins with basic chemicals. Is there any regulation of basic chemicals in our country? Absolutely; starting with the Toxic Substances Control Act, enacted in 1976 precisely to fill the gaps of all the other regulatory controls enacted over the years and to make sure that there was no lack of regulation. Before a new chemical of any kind may be put to any use in this country, it must survive a pre-market notification submitted to the Environmental Protection Agency (EPA), and it must not be vetoed for marketing. The Environmental Protection Agency has the identical authority over all new chemicals that the FDA had over all new drugs between 1938 and 1962. Not pre-market approval, but pre-market notification and veto—a slightly different form of regulation, but one which is effective nonetheless. And very stringently used by EPA these days. Therefore, basic chemicals are fully subject to regulation by the United States Government.

Next, an examination of plants and animals. Just plants as they sit there in the field, and animals as they walk around. Suppose we start tinkering with them, as we all know we are. Are they regulated? There are actually more regulations and more regulatory laws authorizing USDA in particular to regulate plants and animals as such than there are anything else in this entire system.

I will name some of these. The Organic Act allows USDA to prevent plant pests; the Plant Pest Act, the Plant Quarantine Act, the Noxious

**It makes sense to take all of these crazy statutes and try to put them all together and make sense out of them.**

Weed Act, the Federal Seed Act, Animal Quarantine laws, the meat and poultry, egg and food laws, the Endangered Species Act, and then the Department of the Interior has the authority to restrict the import and introduction of exotic plants or animals into the natural ecosystem. There are enough laws here. In

fact, we have more than enough laws. It makes sense to take all of these crazy statutes and try to put them all together and make sense out of them. Something that Congress has never considered, and in its current state of affairs, probably will not get around to.

It is silly to think that entire new plant systems or animals could be injected into our environment without government control. Having at one point served on an Office of Technology Assessment (OTA) Committee looking precisely at the issue of whether there were regulatory gaps in this area, we could find none.

The introduction of plants and animals into consumer products—do we have authority there for the government to control the issue? We have the FDA, of course, and its control over food safety, that I will come back to in a moment; EPA continues to control pesticides; the Consumer Product Safety Commission was authorized in 1972 to control all consumer products not otherwise regulated by USDA or FDA; and we have USDA authority with continuous inspection over meat, poultry, and eggs. The odds of anything slipping through that system are very small indeed.

Let us go on to the workplace, where these products are produced. The Occupational Safety and Health Administration (OSHA) was created in 1970 precisely to deal with all workplace effects. In 1985, OSHA announced that its controls applied to all use of biotechnology in any workplace whatever including the research laboratories.

Let us look then at the environmental effects. Effects in the air, the water, the so-called, one of the great misnomers of all time—“deliberate release” problem. The Environmental Protection Agency has plenary authority under Clean Air Act, Clean Water Act, Resource Conservation and Recovery Act (RCRA), Superfund, the Marine Protection Act and a variety of statutes and regulations that we need not get into. The environment is as clouded with regulatory control as is the food and drug supply.

Transportation—is there any way that these rambunctious recombinant DNA molecules can be transported around the country under unsafe conditions? Well, the post office itself has already issued regulations saying

**Section 361, which I actually authored in the debates in 1976, is the single regulatory control mechanism for all of the new biotechnology.**

you cannot mail them. The Center for Disease Control (CDC) has control over all etiologic agents of any kind; nobody can deal with them without CDC approval. The Department of Transportation deals with them under the Hazardous Materials Transport Act. So we have more than enough authority there.

Now you might say that pretty much covers everything. But additional regulatory controls in the United States make sure there are no cracks in this entire regulatory edifice. To make certain that everything else is controlled, Section 301 of the Public Health Service Act in effect authorizes the Public Health Service to do anything they need to do to protect the public health. Section 361, which I actually authored in the debates in 1976, is the single regulatory control mechanism for all of the new biotechnology. It states that the public health service, including FDA, may take any action of any kind whatever, intra-state or inter-state, in order to prevent (not control) the spread of communicable disease of any form. It is a holdover from 100 years ago, in the days when we were terribly concerned about the spread of infectious disease. That statute, one sentence long, could be used to control all aspects of biotechnology.

Thus we have a regulatory scheme in place in the United States today that is more than sufficient to control biotechnology. The real problem is enormous overlap of among these statutes. There is virtually nothing that cannot be controlled. I will get to two issues that have been raised about that. My judgement is there is no gap here, only the real problem of administrative overlap and therefore the need for administrative comity. I always pronounce that very carefully; we have enough administrative comedy. The problem is one of coordination, making certain that we do not kill an industry, kill a research, kill the greatest opportunity for humankind to improve public health that the world has ever seen.

There have been many people who have suggested that on top of all of this, we need new statutes and regulations to deal with biotechnology per se. I find that ludicrous. The attempt by the United States Senate in particular in 1978, to enact legislation designed to deal precisely with a broad new overarching control of biotechnology in my judgement would have nipped the scientific promise of biotechnology before it could have begun. That was successfully avoided by scientists uniting in their opposition; by discussions in particular with Senator Edward Kennedy, scientific progress and the need for flexibility; and by taking upon themselves in one of the



most extraordinary and wonderful events I have ever seen in the field of science, self-regulation through basically a voluntary regulatory system set up by the NIH in the form of the recombinant DNA guidelines; the development of the Recombinant Advisory Committee (RAC). If science had not acted responsibly, and had not done that, we would have seen the Senate enact legislation and we would not have the progress that we have seen to date.

The two issues mentioned as needing additional controls are: worker surveillance, (as though OSHA did not exist and did not have its authority), and "deliberate release", (to return to what I regarded as one of the great misnomers of all time). I keep pointing out the whole purpose of biotechnology is to release something into the environment, otherwise if you contained it, it would not very useful. Nonetheless, that has become one of the issues in terms of adequate regulation.

Our OTA committee reviewed the issues in detail and concluded that once again, we have more than enough laws. If we needed to energize some of our regulatory agencies to utilize those statutes, to take the opportunity to increase regulation in particular areas where it was needed, that was fine. But we did not need new laws and regulations.

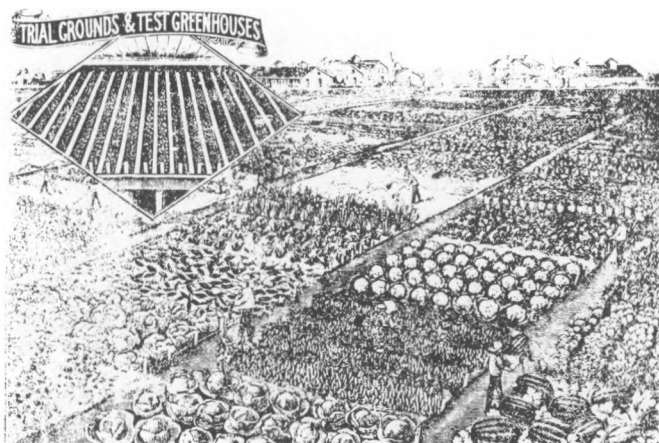
Now let me turn very briefly to FDA and the regulation of food in particular. No new food ingredient—whether we call it a whole food or a food substance (we are not going to call it a food additive because that prejudices the issue), may be used in the food supply in the United States whether in meat or poultry or any other food unless it satisfies one of three criteria: 1) it must have been approved by USDA or FDA between 1938 and 1958, (i.e., a prior sanctioned substance); or 2) it must be "generally recognized as safe", a GRAS substance; or 3) it must be the subject of a food additive regulation. If it is not one of those three, it is illegal.

It is very simple. We have a wonderfully easy system, when you get right down to it. All you have to do is understand those three concepts. Now obviously there were no recombinant products prior to the Food Additives Amendment of 1958, and so one might easily conclude that ends at all. New biotechnology has to be regulated through a food additive regulation. Not true.

When one takes a plant and alters it, one can do that by natural breeding or selection or one can do it by recombinant DNA. When FDA issued its regulations well before biotechnology in the early 1970s, the agency anticipated the kinds of issues from breeding and selection and said that it is a

matter of judgement—a matter of science, not of laws and regulations—as to when a food ingredient is so changed that it is no longer subject to a prior sanction or a GRAS determination and requires a food additive regulation. Or when it changes just slightly, but not enough to worry about, it can remain subject to that prior sanction, or subject to an existing GRAS determination, or indeed subject to an existing food additive regulation, and does not need a new regulation.

Now FDA issued those regulations before Paul Berg did his work and the Recombinant Advisory Committee was formed. The regulations have not changed and they do not need to be changed. Some have argued that FDA should be more explicit; they should lay down heavy, rigid rules, telling everybody when things have changed so much that you need a new regulation and when they are sufficiently similar that you do not need a new regulation. I think that would be foolhardy. I think we would have rules and regulations that would tie us in knots rather than being helpful. Flexibility is a far greater attribute in government regulation than rigidity. It is, I hope, as meaningful to all of you as it has been to me, that the first FDA approval of a recombinant product came not in the form of a new, rigid, regulation, but in the form of a GRAS determination, thus sending a signal that FDA is prepared to remain flexible in its regulation in the future.



## Biotechnology and Food Safety

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Great economic and social forces flow like a tide over half-conscious people. The wise are those who foresee the coming event and seek to shape their institutions and mold the thinking of the people in accordance with the most constructive change. The unwise are those who add nothing constructive to the process, either because of ignorance on the one hand or ignorant opposition on the other.

English economist and philosopher John Stuart Mill

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Biotechnology will yield an expanding array of new foods, food ingredients, food additives and new processes to produce existing products. These include bruise-free fruit, crisper celery and sweeter carrots, caffeine-free coffee beans, and low-calorie sweeteners. The Food and Drug Administration (FDA) recently approved rennet, the first biotechnologically produced enzyme approved for use in food. Much animal biotechnology research focuses on producing transgenic livestock and poultry that will utilize feed more efficiently, grow to desired slaughter weights at an earlier age, and be resistant to a variety of diseases. Farmers stand to benefit from reduced production costs, improved efficiencies, and higher quality products. Consumers will benefit because farmers will be able to supply leaner meat and poultry produced with a decreased dependence on vaccines, drugs and insecticides. In addition, consumers may see reduced prices at the grocery store, since farmers will produce animals of the same weight as is currently produced, but in a shorter period of time with lower production costs.

While these products and events are exciting possibilities, difficult decisions lie ahead in biotechnology. For example, bovine somatotropin (BST) which only needs to pass long-term animal health tests before re-

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**To best prevent food safety problems, government, industry and consumers must acknowledge their respective responsibilities for ensuring safe food.**

ceiving FDA approval, holds great promise for dairy farmers. Bovine somatotropin has been declared safe by FDA; yet it continues to be the target of food safety accusations.

Food safety is an easy target for biotechnology critics, as consumers are already confused and worried about food safety. A recent survey by the Food Marketing

Institute reported that only 15 percent of those surveyed were "completely confident" that the food sold in grocery stores is safe. Sixty-four percent of consumers said they were "mostly confident" about supermarket food.

A recent Michigan Department of Agriculture survey indicated consumer confidence in food had declined and that food safety depended upon government inspection and regulation. Those surveyed said increased food product testing was the single best method to improve food safety. From the perspective of the FDA this may appear to be a positive finding, however, it gives rise to a concern that some consumers feel that more sampling and testing is the single key to safer food.

Sampling and testing are important for detecting potential violations and problems, but detection is not the optimal way to ensure food safety. At the Food Safety and Inspection Service (FSIS), the emphasis is on preventing rather than detecting food borne contamination. Prevention is the best way to deal with drug abuse, and it is the best way to ensure food safety. To best prevent food safety problems, government, industry and consumers must acknowledge their respective responsibilities for ensuring safe food. The inspection services are becoming more science driven, and intend for their evaluation of biotechnology products to be based on sound science.

The Food Safety and Inspection Service is responsible for ensuring the safety and wholesomeness of meat and poultry. Last year, 121 million head of livestock, almost 5.9 billion birds, and 150 billion pounds of processed product were inspected. The Food Safety and Inspection Service is the agency that provides the final assurance that the meat and poultry products of biotechnology are safe. Some food safety responsibilities are shared with other agencies. In order to ensure that plans for new products are well coordinated, a Food Animal Biotechnology Information Exchange Group has been organized. Representatives from USDA, which includes FSIS and the Animal and Plant Health Inspection Service (APHIS); FDA

which includes the Center for Veterinary Medicine and the Center for Food Safety and Applied Nutrition; and the Environmental Protection Agency (EPA) meet regularly to consider jurisdictional issues and anticipate problems and concerns.

Bringing improved foods to market requires the scientific assurance of safety. Biotechnology products are expected to be safe, but that safety

**Biotechnology products are expected to be safe, but that safety must be demonstrated and documented to ensure public health and to win public confidence.**

must be demonstrated and documented to ensure public health and to win public confidence. At FSIS, animal products of biotechnology will be reviewed and approved under existing regulations. A formal position is currently being developed regarding how products of biotechnology that affect the meat and poultry industry will be reviewed and evaluated. The current position is based on technology as it is now, but the position will evolve over time to keep pace as

new technology becomes available and as scientific findings point to the need for changes. We want our regulatory process for biotechnology to be a public one. Surprises do not do anyone any good. We cannot afford to operate behind closed doors with consumers questioning our actions or decisions. We intend to share our recommendations with USDA's Agricultural Biotechnology Research Advisory Committee to ensure all scientific considerations have been taken into account. Scientific considerations are our number one priority.

Food safety decisions must be based on the best science available. Emotional and socioeconomic issues, while important, cannot play a role in determining the food safety of biotechnology products.

There are two main areas to review in the current thinking on evaluating the safety of biotechnology products for the meat and poultry industry: substances added to meat and poultry products, and transgenic animals that carry a desired gene.

Substances added to meat and poultry products With a biologically-derived enzyme, flavoring or other food additive, FDA is the agency responsible for approving the products for safety. Once the products have been approved by FDA, a safety and efficacy evaluation will be conducted for the specific use of the product in meat and poultry products at defined concentrations and specific formulations. This secondary review certifies the substance as safe and effective in meat and poultry in its planned use and that it presents no nutritional or other concerns.

**Transgenic Animals** The safety assessment of transgenic animals should be conceptually very similar to the evaluation of traditional animals. Biotechnology merely provides methods for making well-understood and precise genetic changes. In most cases, the changes themselves will be modest, directed at health, disease prevention and nutritional quality. In fact, the precise nature of the genetic change is known with transgenic animals, directing the safety inquiry to the appropriate issues. Traditional breeding provides no such clues. Also, if the animal containing the desired genetic material is healthy, it is very likely the animal will be safe to eat. Just as is the case with traditional animals, the health of the animal is an important indicator of its safety.

The safety evaluation of transgenic animals focuses on two topics: the genetic insert and the nature of the gene product. The genetic insert is the piece of DNA added to the genome of transgenic animals. Unless it is infectious, it is of no consequence. The DNA of animals and plants that are consumed is all part of the food.

**We want our regulatory process for biotechnology to be a public one. Surprises do not do anyone any good.**

Although the gene product must be examined carefully, the safety questions are not new. Genes produce proteins, the evaluation of which is not new. Genes produce proteins and the evaluation of proteins is a routine food safety consideration. The FDA will be consulted on animal drug and other pharmacological products, and EPA on gene products that have pesticidal activity. If the protein product is alleged to be identical to other proteins already in the diet, we will require data to support its identity. In all cases, we will use existing tolerances and safety considerations for gene products that have the same effect as traditionally produced drugs, pesticides or additives.

Should biotechnology provide new products for which there are no tolerances or safety guidelines, we will require the appropriate toxicity and pharmacokinetic data to ensure the safety of the product.

To summarize our regulatory plans, FSIS expects that once the safety of the gene product is established, transgenic animals are likely to require similar safety considerations as traditional animals.

The use of biotechnology is not always an appropriate trigger for oversight. However, the method of production should not be ignored. As in the safety review of traditionally produced food additives, the safety assessment takes into account contaminants likely to result from the particular

process. The same will be done with products of biotechnology. Plans for regulating biotechnology products will afford consumers the same high level of safety and confidence they have enjoyed for years. Science will drive FSIS decisions. Hopefully science will drive regulatory decisions worldwide.

Biotechnology is international in scope and it is imperative that its safety be judged with scientific standards. We intend to work with Codex and other international organizations such as the International Plant Protection Conference and the International Office of Epizootics to review international food standards as they relate to biotechnology. These groups can help coordinate scientific standards that ensure the food safety of biotechnology products. Harmonized food safety standards will help settle international disputes, reduce trade conflicts and improve consumer confidence.

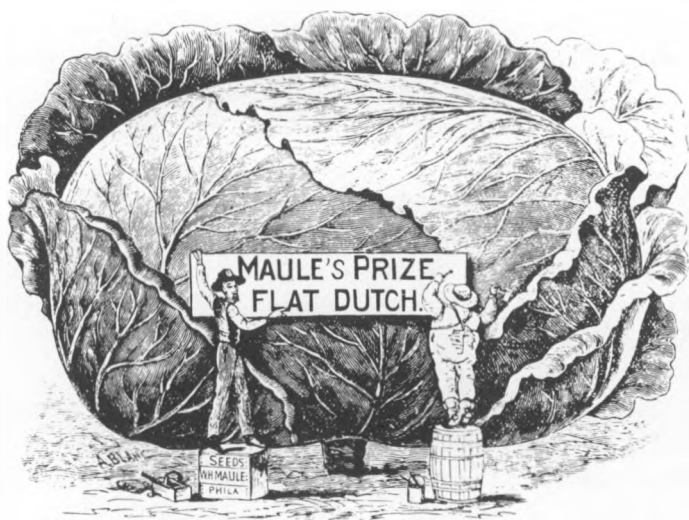
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Codex will hold a biotechnology consultation in November, 1990, at which experts will discuss the food safety implications of biotechnology and will determine whether there are any food safety questions that cannot be handled by the current Codex organizational structure. The United States is also working with the European Community (EC) to resolve food safety disputes. Secretary of Agriculture Clayton Yeutter and Under Secretary Richard Crowder met in early June with their counterparts from the Office of European Community Development. The Secretary has also set up regular consultations with the European Community's Director Generalship for Agriculture to discuss food safety. These forums should prove useful in discussing potential disputes early rather than waiting for conflicts to arise.

Biotechnology will see its share of conflict. It is a new technology that is entering the marketplace at a time when consumers are anxious about the use of technology in food production. Consumers want "natural" products that are free of synthetic additives. They also want nutritious, convenient, high quality, well-packaged foods—all of which require technology. Biotechnology will help give consumers what they want.

Biotechnology will help fight bacteria that contaminate food. Biotechnology can reduce the fat in meat products and add nutritional value to other products. A long road lies ahead in convincing the American public that technology and its use in food production is not bad, and FSIS is committed to helping consumers understand the role of technology—including biotechnology—in food production and safety. Biotechnology critics are

poised to impugn food safety as a rallying point against the new technology. The government, along with the food and biotechnology industry, must use sound science to prove food safety and to stand behind our public health decisions. If emotions were allowed to overrule sound science, unjustified food safety scares are risked along with a total loss in consumer confidence. We would also be breaking our trust with the public, which expects us to do the right thing, even when it is difficult and controversial.





## Evaluating the Relative Safety of Biotechnologically Produced Foods

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There was a time when food safety was a relatively concise discipline. In those halcyon days, foods were considered safe unless eating them made one ill. People based the selection of their daily fare on fondness, not fear. But times have changed. Today, many people eat to prevent disease, especially chronic diseases such as atherosclerosis and cancer. Food safety has come to encompass much more than the prevention of foodborne illness.

I recently heard a lecture by one who tends toward zealotry on the subject of nutrition. He charged that our food supply is inherently unsafe because of its composition. The enthusiast of whom I speak happens not to like fat very much—nor salt, nor meat, nor a host of other things including the cooking practices Americans routinely use, and he blamed all of this for causing cancer, heart disease, or both.

Now I happen to support the notion of eating a well balanced diet in moderation. But there is no reason to be an extremist on the topic. Moreover, it seems self-evident that a nation blessed with the world's largest and most diverse supermarkets cannot, at the same time, suffer from a compositionally unsafe food supply. That is, unless every single food is unsafe—and if such is the case, one might wonder why the Social Security system is in so much trouble. But regrettably the unsafe food charge is heard again and again, and it is having an effect. An effect, I would argue, that is not particularly healthy.

Continual harping from some quarters about the supposed “unsafeness” of the traditional food supply -

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**If the public worries about the safety of the traditional food supply, it will worry ten times more about the safety of new foods.**

be it too much saturated fat or too many pesticides - has eroded public confidence in its own institutions like the Food and Drug Administration (FDA) and the United States Department of Agriculture (USDA), as well as trust in the food industry, and even the pronouncements of academic scientists. (That last hits too close to home.) The simple fact is that every person in this room who wishes to market a novel food is affected by a malignant climate of mistrust that pervades the land. If the public worries about the safety of the traditional food supply, it will worry ten times more about the safety of new foods.

So we really have two tasks: convincing ourselves that a novel food is safe, and then convincing the public that it is safe. I will address the former task.

It is essential that the burgeoning food biotechnology industry develop a firm grasp of the scientific data base underlying food safety. Additionally, the scientific data base must not be confused with, or dismissed because of, concerns raised in the context of arguments that really center on non-scientific matters. I am thinking here of economic or political issues where food safety may be inappropriately raised in an attempt to bolster a particular point of view. A good example is the furor in Wisconsin over the use of bovine somatotropin.

Table 1 shows a ranking of food safety concerns. It was developed by FDA in the mid-70s. According to FDA, the most important food safety hazard is microbial contamination. This conclusion is based on tangible evidence, not theoretical possibilities. Foodborne pathogenic microorganisms and their toxins cause substantial amount of illness and economic loss (Archer and Kvenberg, 1985; Todd, 1985).

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**Table 1 FDA Ranking of Food Safety Priorities**

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1. Microbial Contamination
2. Nutritional Imbalance
3. Environmental Contaminants
4. Naturally-occurring Toxicants
5. Pesticide Residues
6. Food Additives

(Schmidt, 1975)

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Next in line from microbial contamination is nutritional imbalance. By this the FDA means two things. First are the crazy, dangerous diet plans that many Americans are lured into trying each year. Serious illness and even death is a tragic, but well documented, by-product of such ill-advised personal experimentation. But in addition to this there is also the general problem of poor eating habits, in particular gluttony, which when combined with the lack of physical activity can compound a genetic tendency toward certain chronic diseases. An outcome of poor eating habits and too little exercise is obesity with its clear link to heart disease, diabetes, and some forms of cancer. Unfortunately obesity affects too many Americans.

In contrast to microbiological contamination and nutritional imbalance—risks for which clear and unequivocal scientific evidence certainly exists—there are only theoretical calculations for the possible adverse effects of environmental contaminants, naturally-occurring contaminants, and pesticide residues. One of the most comprehensive scholarly reports in the peer-reviewed scientific literature to address this issue—an epidemiological report published in 1981 by Sir Richard Doll and Richard Peto—estimated that the cancer risk associated with these sources is extremely small. And as for food additives, there is no evidence that they are harmful under the intended conditions of use. To the contrary, some additives (e.g., antioxidants) actually protect against cancer in animal experiments and may also reduce cancer risks in humans (Ames, 1983; CAST, 1987).

Given all of this, one might imagine a slightly different depiction of this table. Table 2 is the expert's view of food safety. It comes closer, but still does not do the situation true justice. Indeed, if microbiological concerns were set at, say, a million, then food additives would be "worth" at most one, if that much.

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**Table 2** Proportional Representation Of Food Safety Issues

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microbial contamination  
nutritional imbalance

environmental contaminants  
naturally-occurring toxicants  
pesticide residues  
food additives

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Table 2 is based on science, and anyone who takes the time to become familiar with the scientific data is bound to concur. Unfortunately, the public inverts this ranking believing that the last three are major causes of human health problems. It is going to take a lot of education to straighten this mess out, made all the more challenging because of the cries from those who intentionally distort food safety issues for reasons that are not at all related to food safety or science.

But let us go back to hurdle number one—convincing ourselves that a new food is safe. How can the information in this table be applied to that?

First, let us talk about microbiological issues. In general, foods derived through biotechnology will not carry greater risks of contamination with pathogenic microorganisms or microbial toxins than do conventional foods. In this regard it is worth reviewing the factors that control microbial growth in food: pH, type and concentration of acid, water activity, the concentration of sodium chloride and other electrolytes, the availability of nutrients and growth factors, and the levels of microbial growth inhibitors. Any change in the composition of a food that affects one or more of these factors will influence the chances of that food becoming a vehicle for foodborne illness (Pariza, 1990).

For example, most varieties of tomato exhibit a pH value no higher than 4.5 which is sufficiently low to preclude the growth of pathogens such as *Clostridium botulinum*, the causative agent for botulism. However, the pH of some tomato varieties is above 5, clearly too high to prevent the growth of *C. botulinum* and many other pathogens (Powers, 1976). Hence, foods prepared with high pH tomatoes may have to be handled differently than foods prepared with conventional tomatoes. It is very important to keep this sort of thing in mind when developing low acid varieties of fruits and vegetables.

A second consideration is the intentional removal of a microbial growth inhibitor. For example, one might imagine some bright geneticist coming up with the idea of intentionally removing genes involved in caffeine synthesis from coffee plants. The development of such a “naturally” decaffeinated coffee bean might be desirable for a variety of reasons including making the marketing department happy. But it could also have a down side. Caffeine is reported to be an effective suppressor of aflatoxin biosynthesis by certain toxigenic molds (Nartowicz et al, 1979). Hence, coffee beans without caffeine could be at greater risk for contamination with aflatoxin, which is a potent carcinogen in laboratory animals.

Another potential problem could arise from the intentional introduction of a new nutrient into a food plant. Suppose, for example, that the nutrient should happen to be a required growth factor for a particular pathogen. Suppose further that the pathogen does not now grow in the traditional food because that nutrient is lacking. The conclusion is that some other means will now have to be found to control the pathogen in the new food containing the nutrient.

Fortunately there are bright sides too. Biotechnology has great potential to aid in controlling the contamination of food by some microbial toxins. A case in point is a project in my department aimed at preventing aflatoxin production in the field, thereby controlling this mold-generated carcinogen at the source. Later this year we hope to begin testing the idea in the

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**There is also a big future for biotechnology in the development of special foods for persons with special medical problems (e.g., peanuts minus the major peanut allergens) foods for those who must avoid certain other dietary factors, and so on.**

controlled environment of our Biotron.

The next major issue on FDA's list is nutritional imbalance, which includes poor eating habits. An important consequence of poor eating habits is obesity which is linked to increased risk of several chronic diseases including diabetes, heart disease, and cancer. One of the most important contributing factors in obesity is the excessive consumption of dietary fat (Pariza and Simopoulos, 1987; CAST, 1987). Biotechnology can certainly help here, through the development of new lower fat animal and plant based foods.

There is also a big future for biotechnology in the development of special foods for persons with special medical problems, (e.g., peanuts minus the major peanut allergens), foods for those who must avoid certain other dietary factors, and so on. One must also be careful about understanding the nutritional role of traditional foods in the diet. For instance, it would be unwise to inadvertently reduce the vitamin C content of an orange while in the process of introducing other changes.

With regard to environmental contaminants, it is difficult to imagine biotechnology contributing to the problem. But one can easily envision engineering microorganisms, for example, that are able to efficiently degrade industrial waste products.

Naturally-occurring contaminants represent a potential focus of concern. It is well known that some food plants produce potentially toxic substances, some of which are involved in protection against insects (Ames, 1983; NAS 1973). Obviously in developing new plant foods, the level of

naturally-occurring toxic constituents that may be hazardous to humans should not be increased either through direct introduction of relevant genes or through an unintended pleiotropic effect, that is, a secondary phenotypic alteration resulting from a single genetic change (Tiedje et al., 1989). In this regard one should investigate new food plants developed by biotechnology for increased levels of naturally-occurring toxicants known to be associated with the species.

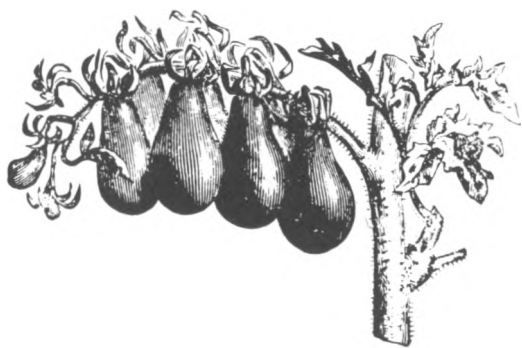
Biotechnology offers opportunities for reducing pesticide dependence through the introduction of naturally-occurring pesticides that exhibit limited host range and are also biodegradable. An important example is the introduction of the gene for *Bacillus thuringiensis* toxins into food plants such as tomatoes and corn.

Finally, on the list is food additives, long the bane of the so-called consumer movement. It is worth recalling that food additives are used because they have important beneficial effects— effects which are not clearly articulated for the public as they might be. Among these effects, for example, is the control of microbial pathogen growth in food. Prospects for the production via biotechnology of safe and effective antimicrobials for addition to food is an area of particular interest in my department. There are, of course, many additional opportunities for the use of biotechnology in the manufacture of antioxidants and other beneficial products.

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## The Implications for Biotechnology-Related Products of Food Safety and Nutrition Based Marketing

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In any consideration of the potential impacts of biotechnology on the food supply, health, safety, and environmental impacts are emphasized first. Economic impacts are next, such as societal benefits and costs, the organization of production, processing, and distribution; and firm profitability and market shares.

For both sets of impacts, at issue is how biotechnology affects the chain of production and distribution running from input manufacturers to producers, processors, distributors, retailers, and consumers. Food safety and nutrition are fascinating because they link health and safety concerns with economic concerns. This is because the economic success of food marketing firms is becoming more closely linked to the safety and nutritional attributes of the products they produce and sell. This is a key point since the closeness of this link is relatively new.

The focus here is on the marketing level aspects of biotechnology, particularly on consumer acceptance which will ultimately determine biotechnology's success or failure in the marketplace. This paper operates with a premise that sets aside considerations of what safety standards government agencies will apply to acceptance of biotechnology-related products. These considerations, while important and a major topic of discussion at this conference, are not directly relevant to this discussion.

Therefore, it will be assumed that the biotechnology-related ingredient, drug, process, or product under discussion has been accepted under roughly the same government safety standards currently in effect for conventional ingredients, drugs, processes, and products.

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**The question then is: How will biotechnology-related products be marketed?**

The question then is: How will biotechnology-related products be marketed? Several earlier presentations, particularly Carol Tucker Foreman and Kenneth

Taylor, noted that biotechnology is coming on the

market in a very specific context, which is the result of consumers' experiences in the 1980s. This context will be considered first, and then marketing issues particular to biotechnology-related products will be discussed.

### **The Current Food Marketing Environment**

In the last decade, increased scientific evidence and consumer awareness of links between diet and health have created an expanded market for food products that fit specific safety and nutrition profiles. The shift in demand coincided with significant changes in the regulatory environment during the 1980s. Firms have developed at least two major strategic responses in the face of these changes in demand and the regulatory environment (Caswell and Johnson, 1990). The first response has been the development of strategies that create product or establishment differentiation based on food safety and nutrition. The second response has been to develop strategies that attempt to manage any potential liability or exposure to government regulation associated with food safety and nutrition issues.

The differentiation-based strategies are domain offensive in nature. Firms using them seek to increase or, at a minimum, maintain their market shares by emphasizing the food safety and nutrition attributes of their products or services. Such differentiation may be based on product characteristics or, in the case of retailers, on the services offered by the firm (e.g., screening of fresh produce for pesticide residues). These strategies emphasize positive information and, where possible, suppress negative information. In the current marketing environment, food safety and nutrition have become a new basis for non-price rivalry between firms in the food system. For example, market shares in the ready-to-eat cereal industry have shifted based on the leading firms' relative success in marketing high fiber cereals.

This new emphasis on differentiation and marketing based on food safety and nutrition developed in the 1980s because of several factors. First, as noted above, scientific and consumer knowledge improved and consumers subsequently altered their demand for some food products in response. Second, the federal government's policy on health claims made by firms on their food labels changed. After 1984, and certainly after 1987, such health claims became legal under lenient standards and enforcement

by the Food and Drug Administration (FDA). This change gave firms a much broader scope for effectively communicating differentiation based on food safety and nutrition. Third, and at the same time, the Federal Trade Commission was lax in pursuing deceptive advertising cases against major food products. These latter two factors combined to create a virtual free-for-all atmosphere for firms wishing to pursue differentiation strategies.

Fourth, and finally, there was an increased perception among consumers in the 1980s that the federal regulatory system was not adequate to insure food safety. Many commentators, and several speakers at this conference, have implied that this erosion in confidence was the result of hyping of the food safety issue by the media and special interest groups. In fact, however, the erosion in confidence was due in large part to inadequate government regulation during the 1980s, which was documented in a long series of reports (U.S. General Accounting Office 1986a, 1986b, 1989; National Academy of Sciences, 1987).

Examples of marketing based on food safety and nutrition attributes are abundant. Growers and manufacturers have engaged in product innovation to produce frozen foods that meet nutritional recommendations (e.g. ConAgra's Healthy Choice line), baked goods that contain no fat or cholesterol (e.g., Entenmann's No-Fat, No-Cholesterol line), and beef products produced without use of hormones, antibiotics, feed additives, or preservatives (e.g., Coleman's Natural Beef). Distributors and retailers have similarly engaged in differentiation by offering services to consumers such as in-store nutrition information programs and testing of fresh produce for pesticide residues.

The second major strategic response of food firms to changes in demand and regulation has been to develop strategies which aim to manage any po-

**Biotechnology related products will have to compete not just against traditional or conventionally grown products but also against an array of products that are sold based specifically on their food safety and nutrition characteristics.**

tential liability associated with food safety and nutrition or attempt to protect the firm from the impacts of government regulatory activities. This strategic response tends to be defensive in nature and focuses on the management of negative attributes and information. While often designed to protect specific aspects of the firm's operations, these strategies may also attempt to influence public opinion on the general issue of food safety and nutrition, often through repeated assurances that the food supply is safe.

Thus the marketing of biotechnology-related products will take place in the context of a market that is sensitized to food safety and nutrition issues. It is a market made up of firms and consumers who now have experience with marketing and differentiation based on food safety and nutrition attributes. Biotechnology related products will have to compete not just against traditional or conventionally grown products but also against an array of products that are sold based specifically on their food safety and nutrition characteristics.

### **Marketing Biotechnology-Related Food Products**

A crucial decision facing firms is how to market biotechnology-related food products. There appear to be two basic choices. First, firms can treat biotechnology related production processes and products as if they were just another process or product. In this case, marketing would emphasize the positive attributes of the product but not focus on its unique or new origins. Second, firms may differentiate the product based on its biotechnological origins. This may work well if the firm has some exclusivity (or at least temporary exclusivity) in marketing the product. For example, marketers may be able to stress positive food safety and nutrition attributes resulting from the biotechnological origins of the product, e.g., grown with fewer pesticides or containing a higher nutrient content.

But marketers must be aware that even if they prefer the first approach events are, at least in the foreseeable future, unlikely to allow a firm to simply finesse the biotechnology issue. The experience to date with bovine somatotropin (BST) bears this out, as will be discussed further below. The difference in today's market is that passing a government approval process, even when the process is stringent, is no longer enough for the consumer. Wishing that it was, is simply howling at the moon at this point in time. As several speakers noted yesterday, consumers will evaluate these products and the processes with which they were developed based on a range of risk and value considerations.

Unfortunately, there appears to be a great deal of resentment in some parts of government and the food industry that this is the case. Without question, there is ample room for a better understanding of food safety, nutrition, and biotechnology among consumers. But this is not a one-way street with experts presenting information and "straightening out consumers' perceptions". To look at the process this way is to take a condescending view toward consumers' own safety and value agenda. This agenda may not be that of the scientists but it is no less valid.

**Who is going to sell biotechnology to the public? The candidates are drug or ingredient manufacturers, growers or farmers, food manufacturers, retailers, trade associations, government, or public interest groups.**

As we look to the marketing of biotechnology-related food products, there are two major issues. First, again assuming that the food product has been approved for sale by the government: Who is going to sell biotechnology to the public? The candidates are drug or ingredient manufacturers, growers or farmers, food manufacturers, retailers, trade associations, government, or public interest groups.

The experience to date with BST illustrates the difficulties associated with this question. It is not at all clear who will market BST to the public (Richards, 1989a). It appears to me, as an outsider, that the introducers and users of BST hoped this was an issue they could finesse. In other words, they hoped they could treat BST use as just another production process not requiring any special consumer marketing program. They have found that in the current marketing environment this cannot be done. Several firms are reported to have refused to handle milk from cows treated with BST, either entirely or until FDA approval. These firms include one dairy cooperative (Associated Milk Producers Inc.), at least three processors (Kraft, Borden, and Ben and Jerry's Homemade Ice Cream), and four retail chains (Safeway, Stop & Shop, Kroger, and Van's). In a situation where processors and retailers are increasingly basing major parts of their marketing strategies on food safety and nutrition, firms will be very hesitant to risk their hard-earned differentiation by selling products that raise safety concerns while yielding only small benefits to themselves. The firms mentioned above apparently found this private benefit/cost tradeoff to be negative for BST milk, at least in its initial period of use.

So, who will sell BST to the public? Supermarkets complain that the makers of BST are dumping the responsibility for allaying consumer fears regarding BST on them. An official of the Kroger Co., for example, is quoted as saying, "If they think it's safe, let them step up the plate and defend it" (Richards, 1989b) and, "If we're going to make any mistakes on this, we're going to make them on the side of safety" (Ingersoll, 1989). The firms' differentiation strategies make them reluctant to accept any risks to their reputations that might be associated with marketing biotechnology-related products that have not already been broadly accepted by the public.

The second major marketing issue facing biotechnology-related products is: What information disclosure will be required in the presentation of

**In marketing, the the products? And, in addition: Who (federal or state biotechnology issue government) will require this information? Labeling can not be simply fin-** is an attractive option in the current market atmosphere of increased consumer awareness because it is responsive to consumers' desire for control. It is also attractive to regulators who wish to place more reliance on markets rather than government agencies for making choices regarding food safety and nutrition.

We are, I think, groping for a policy on when provision of information through labels is a desirable regulatory strategy. Many firms have not presented a consistent front on this issue. If firms believe that more information is better for the consumer in the area of health claims, can they in good faith object to the labeling of biotechnology-related products? My prediction is that for controversial biotechnology-related products, labeling will be widespread. Either government units will require labeling to identify such products or some firms will voluntarily label that they do not use any biotechnology-related processes or ingredients in their products. In either case, consumers are likely to be able to identify products that are biotechnology-related from those that are not. Again, in marketing, the biotechnology issue cannot be simply finessed.

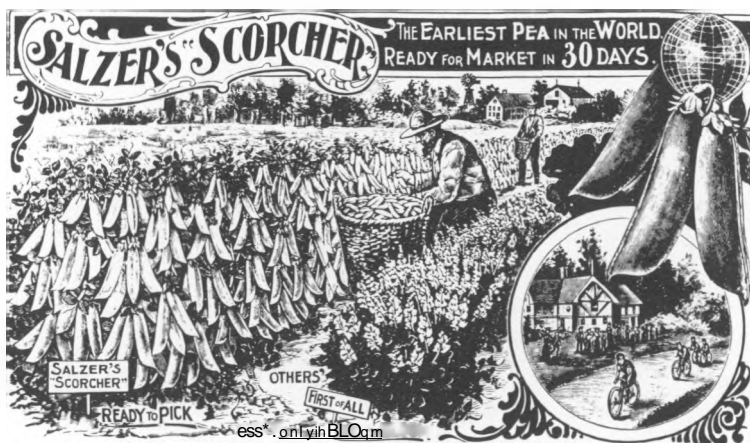
The key question, ultimately, is how biotechnology-related products will compete in a marketplace made up of traditional and conventionally processed products and those that are being marketed specifically on the basis of food safety and nutrition attribute. This is a clouded question at this point in time.

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## Potential Economic Impacts of Agricultural Biotechnology

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An integral part of modern society is the socio-economic change associated with scientific advance. Biotechnology promises potentially significant changes in agricultural production and food processing. Emerging applications of biotechnology to crop and livestock production are capturing the attention of researchers, the business community, farmers, policy-makers, and various special interest groups. Yet, surveys indicate that many people are unaware of agricultural biotechnology, while others are concerned about its potential negative impacts on food safety, small farmers, and rural communities (Office of Technology Assessment, 1985, and Hassebrook and Hegyes, 1989).

Four fundamental questions appear to surround the agricultural biotechnology debate: Is it safe? Is it ethical? Who wins? Who loses? This paper focuses on the latter two questions: Who wins? Who loses? More specifically, some of the potential socio-economic impacts of agricultural biotechnology on farmers and consumers are addressed.

The paper is divided into three parts. First, a few crop, livestock, and food processing examples of biotechnology applications are very briefly reviewed to place in context the subsequent discussion of the socio-economic issues. Next, some of the socioeconomic implications for farmers and consumers are addressed. Then, a few of the technology assessment research and extension issues are outlined. The paper closes with a few concluding comments.

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## Some Examples of Biotechnology Applications

Our discussion of the potential economic implications of agricultural biotechnology must be cast in the context of an often emotionally and politically charged and technically and economically difficult paradox: too

**The challenge before us is to increase agricultural production to meet the growing world-wide demand for food without harming the environment and without exhausting nonrenewable resources.**

much food for a few in the developed countries and too little food for many in the developing countries where 85 percent of the world's population lives.

Feeding a growing world population has been a concern of agriculturalists and others for centuries. During the past several decades, scientists, farmers, the agribusiness sector, and government agencies have worked together to achieve enormous agricultural productivity increases, especially in the more developed economies. Often this has resulted in surpluses and extensive and often costly, government efforts to

restrict production and support farm prices and income. Yet, the world population has passed the 5 billion mark and is expected to double by the mid-21st century. The challenge before us is to increase agricultural production to meet the growing world-wide demand for food without harming the environment and without exhausting nonrenewable resources. Furthermore, this must be accomplished in a world where countless agricultural and trade policy distortions exist. These are currently under discussion in the General Agreement on Tariffs and Trade (GATT) negotiations in Geneva, Switzerland.

Biotechnology holds promise for contributing to additional agricultural productivity increases. But it is important to remember that biotechnology tools complement and extend, rather than replace, traditional methods used to enhance agricultural productivity and to develop new production systems. While some see biotechnology as a revolutionary development, others, including myself, see the development and application of biotechnology tools as an evolutionary process in a stream of agricultural technology developments that began with the mechanical inventions of McCormick and Deere and the genetic discoveries of Mendel. But, of course, modern agricultural production and food processing systems have their earliest roots in humankind's domestication and genetic selection of plants and animals and food fermentation processes that span many centuries.

In plants, genetic engineering can be used to enhance classical breeding. Engineering plant resistance to herbicides, insects, diseases, and environ-



mental stress shows great promise. Excessive or improper herbicide and insecticide use can cause environmental damage. Altering the genetic make-up of plants to render them resistant to insects will lessen the need for chemical insecticides. Except for some concern about possible buildup of insect resistance to genetically-altered plants, there is relatively little controversy about the development of insect-resistant plants and bioinsecticides.

Controversy is growing concerning the development of herbicide-resistant plants, however. The critics suggest that this will result in more herbicide use and more soil and water pollution (Hassbrook and Hegyes, 1989, p 26). They also worry about excessive dependence on monoculture of row crops such as corn or cotton, rather than the use of rotations that include nitrogen-fixing legumes and biological weed and insect control techniques. The critics fear that the development of herbicide-resistant crops will not encourage a more sustainable agricultural system. In contrast, advocates claim that with herbicide-resistant plants, more environmentally benign herbicides can be used. They believe that fewer and less toxic compounds will be applied. Frequently, this debate centers around who will control the technology, i.e., what control the agricultural chemical and seed companies will have (Doyle, 1985).

In animals, biotechnology has already made economically feasible the use of bovine somatotropin (BST) to increase milk production and feed efficiency in dairy cattle. Milk productivity increases in commercial herds of 10 to 15 percent are anticipated with a 5 to 10 percent increase in feed efficiency. Use of porcine somatotropin (PST) and ractopamine, two swine repartitioning agents, can result in leaner pork and more efficient feed conversion. Research trials have reported increases in rate of gain of 10 to 45 percent, feed efficiency increases of 15 to 35 percent, backfat reductions of 15 to 70 percent, and increases in loin-eye of 10 to 50 percent. Other promising applications of biotechnology to animal agriculture include disease diagnostic probes, embryo transfer, and genetically-engineered vaccines (Riepe and Martin, 1989).

Some believe that biotechnology will have its greatest impact on increasing food processing efficiency. There are several ways this could be achieved: altering raw materials, such as the water content of tomatoes;

**Thus far, there seems to be less controversy surrounding the applications of biotechnology to food processing. This is somewhat surprising given the growing national interest in nutritious diets and food safety.**

altering enzymes and microorganisms used in bioprocessing, such as chymosin for cheese production; or discovering new uses for food processing wastes, such as whey from cheese production. Thus far, there seems to be less controversy surrounding the applications of biotechnology to food processing. This is somewhat surprising given the growing national interest in nutritious diets and food safety. Yet, much of the diet debate has been on cholesterol and red meat consumption, fiber intake and oat bran consumption, weight control and exercise programs, and fat and calorie intake. Much of the food safety debate has been on pesticide residues. This may change, however, as biotechnology is increasingly used to alter the ingredients in processed foods and food processing techniques. A current example of this are the concerns raised by some about the safety of milk from BST-treated cows.

### **Producers and Consumers**

Many biotechnology innovations will be cost-reducing which will benefit farmers and food processors initially. However, consumers can ultimately benefit through lower prices and improved food quality and variety. This has been the pattern of most agricultural technology adoption over the past one-half century or more (Cochrane, 1979). However, the magnitude and distribution of these potential cost-saving benefits to producers and consumers will depend on the nature of the technology, its review and approval by government regulatory agencies, its acceptance by producers and consumers, the market structure for the commodity or food, and regulations in the food industry. Consumers will benefit more in relatively competitive markets with price inelastic demand functions.

Much of the concern over agricultural biotechnology is directed towards its potential to accelerate the long time trend towards fewer and larger production units (Office of Technology Assessment, 1985). This trend may increase the influence of large corporations on the decision-making and fate of farmers and residents of rural communities. Technology-driven changes in farm structure are not new. Over the past 3 decades the number of farms in the United States has fallen by 45 percent from 4 million in 1960 to 2.2 million in 1990, while average farm size has increased by over 50 percent. Concurrently, the farm population declined from 19 million to 5 million, i.e., from about 9 percent to 2 percent of the United States population. Also, farm employment declined from 7 million to 2.8 million people (Council of Economic Advisers, 1990 and United States Department of Agriculture, 1974 and 1989). The controversy surrounding BST in

the dairy sector offers an object lesson in the biotechnology and structural change debate (Sun, 1989). Mechanical milking machines, artificial insemination, nutrition research, and other innovations have pushed average milk production per cow from 5,842 pounds in 1955 to 14,244 pounds in 1989, about a 2.5 percent annual increase. Since cow numbers fell by about one-half from 21 million to 10.3 million during this period, the total milk supply increased only about 0.5 percent annually. However, during the most recent 15-year period increases in milk production per cow and total milk supplies both have grown about 2 percent annually. A recent United States Department of Agriculture (USDA) study estimates that with a dairy price support of \$10.10 per hundred weight (cwt) and the introduction of BST, the annual increase in milk productivity per cow would be about 3 percent and the annual increase in the total milk supply would be about 1.5 percent (Fallert et al., 1984). These anticipated increases in milk production and productivity due to BST are not significantly different from the impacts of past dairy technologies. The interpretation of the above data for the dairy sector depends, in part, on one's policy goals and value system. The critics of the introduction of BST emphasize that, in most years, milk has been in surplus, and that in the early-1980s the federal government spent about \$ 2 billion annually to support the price of milk through Commodity Credit Corporation removals of cheese, butter, and nonfat dried milk (United States Department of Agriculture, 1990). Despite these government programs with relatively high milk price supports, the number of farms with milk cows has declined from 1.8 million in 1959 to 202,068 in 1987 (United States Department of Commerce, Bureau of the Census). Those who have left the dairy industry generally have been the smaller, less efficient producers, poorer managers, those with less access to capital, or those less able to make technological adjustments. A coalition of consumers, save the family farm advocates, and critics of biotechnology have successfully influenced legislation in Wisconsin and Minnesota that placed a temporary moratorium on the use of BST

On the other hand, advocates of BST emphasize that most technological advance begins with early adopters who benefit from the new technology by increasing production efficiency, reducing per unit production costs, and increasing per unit profits. Eventually, competitive pressures encourage a wider adoption of the new technology and the efficiency and cost-saving attributes of the technology are passed on to food processors and consumers in the form of lower prices and more abundant supplies.

The advocates of BST claim that this technology is just the latest in a long stream of new technologies in the dairy sector that has influenced the structure of the dairy industry and resulted in a more efficient, competitive dairy sector, with most of the economic benefits eventually being passed on to consumers. Advocates of BST also note that it is not a capital-intensive technology such as the installation of milking facilities, but a relatively inexpensive variable cost of production. However, BST use will require excellent production, record keeping, and financial management skills.

Both critics and advocates of BST recognize the influence that government dairy price support policy has had on the rate of structural change in the dairy sector and on taxpayer costs. Where they disagree is on the desirability of further structural change in the dairy industry and on whether consumers will actually realize any benefits from the technology. Food and environmental safety and government program costs also are sometimes mentioned.

There are some interesting similarities and differences between the public debates over biotechnology products in the swine and dairy sectors. Although PST and ractopomine also are awaiting Food and Drug Administration (FDA) approval in the near future, there has not been the public outcry as in the case of BST. This may be because of less media attention, because pork is not associated with mothers and babies as is milk, or because consumers want leaner pork with less fat. The application of these new technologies in the swine sector will offer larger supplies of cheaper, leaner pork and make pork more competitive with beef and chicken at the retail-level.

The swine industry in the United States has experienced considerable structural change as evidenced by a 50 percent reduction in the number of hog producers over the last 10 years. Potential structural changes in the hog sector due to biotechnology parallel those of the dairy sector, i.e., early versus late adopters, additional management requirements, and increased competitive pressures (Riepe and Martin, 1989). It is also important to examine the effects of a new technology on the input markets such as the demand for various feeds when BST is introduced into the dairy sector or PST and ractopomine into the swine sector (Kuchler and McClland, 1989).

There has been less assessment of the economic implications of the application of biotechnology to crop production and food processing. In many cases the farmer, and consumer, will not even be aware that a

biotechnology tool has been used. An example might be restriction fragment length polymorphism (RFLP) techniques to assist conventional plant breeding programs in improving the disease resistance of a plant. These efforts to rapidly screen genetic material should reduce the research and development costs and time required to produce new varieties, and in this turn should help reduce seed costs to farmers. In other cases, such as insect- and herbicide-resistant plants, the agricultural chemical and seed companies will promote the sale of these genetically-engineered varieties as substitutes for current seed varieties and chemical pesticides.

### The Research and Extension Agenda

Until very recently most technology assessment research by agricultural economists and rural sociologists was ex post analysis. Such studies examined observed adoption rates, surveyed farmers about their production practices and financial conditions, or calculated the benefits and costs associated with a technology that farmers had already adopted. (For more detail on technology assessment see Martin, 1990).

The challenge before us as a research community is to conduct ex ante research. Policy-makers and various public interest groups want to know more about a new technology before it is approved by a government agency. Information on efficacy, proper scientific testing protocols, and possible environmental impacts will continue to be an important part of

**Extension specialists must learn to treat biotechnology as a public policy issue much like we have treated agricultural policy.**

the FDA or the Environmental Protection Agency (EPA) approval process. Furthermore, socioeconomic information, even though not part of the official scientific approval process, will be demanded by legislative and public interest groups.

Such socioeconomic assessment requires much closer interdisciplinary cooperation among social scientists and biotechnology researchers. We must learn to

speak each others' language, to write joint research proposals, and to publish in appropriate cross-disciplinary research journals and extension outlets.

Extension specialists must learn to treat biotechnology as a public policy issue much like we have treated agricultural policy. In the past, extension agents basically helped farmers adopt a new technology without much public discussion of its broader social and economic impacts. Today a much broader clientele wants to influence the development and adoption of agricultural biotechnology. There clearly are issues and choices that soci-

ety must make through both the input and product markets as well as through the “political” markets.

A public policy extension approach that has been successfully used in many states involves public meetings where extension specialists help define the problem and explain policy choices. Furthermore, policy specialists provide objective technical and economic information on the implications of each of the potential policy choices. The goal of these public policy meetings is not to tell people what technology is best for them but to help them make more informed judgments as producers, consumers, and “voters” at the ballot box or through the lobbying process.

As scientists, we sometimes forget that few in society have the training or time to understand emerging scientific developments. Yet the public is a “consumer” of our “product”. Ultimately, it is the public that adopts or rejects the products generated through our research. Moreover, their understanding and approval of what we do influences the allocation of tax dollars to support our research activities.

In a democratic society such as ours, we have an obligation to inform and involve the public in the process of scientific development and technology transfer. The public is no longer willing to accept self-regulation by scientists. But if we can provide objective, understandable information on the potential technical and socio-economic consequences of emerging agricultural biotechnologies, most people will be able to make rational, informed decisions.

For many of us this is a new role, and one which may take us away from our research laboratories. Yet it is critical, if the benefits of biotechnology are going to be enjoyed and the economic, social, environmental, and political costs minimized.

### **Concluding Comments**

It is vital that the public becomes aware of and knowledgeable about the scientific advances of our day and the implications and issues surrounding these innovations. Biotechnology offers great potential to increase farm production and food processing efficiency, lower food costs, enhance food quality and safety, and increase international competitiveness. There are, however, potential environmental risks and adjustment costs that must be assessed. Careful evaluation of the likely benefits and costs of biotechnology can ensure the timely and reasonable application of these emerging technology developments in our society. This will require increased research cooperation among bench and social scientists from a wide range of

disciplines. Moreover, we in the Land-Grant system must design and implement appropriate public policy extension programs to help the public better understand the technical and socio-economic ramifications of alternative choices before us as a society. If we fail in this task, controversy will grow and potential benefits to society will be lost. Yet, it is important to listen and respond objectively to those who are critical of biotechnology. Through this dialog we can perhaps avoid some of the errors or accidents that have occurred with new technologies in the past. Furthermore, by being sensitive to the concerns of those who do not understand or who fear the emerging biotechnologies, we may be able to design appropriate public policies to help people anticipate and adjust to changing market and structural conditions as the new technologies are introduced.

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Seeds for Market Gardeners and all Others.

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# The Social Impact of Biotechnology on Farming and Food Production

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## Introduction

The family farm is disappearing. The family farm is quite enduring. New technology is the cause of social change. New technology is the consequence of social change. Biotechnology is revolutionary. Biotechnology is really more of the same. The world needs more food production. The world already produces enough food to meet its needs. Biotechnology will radically alter living nature. Biotechnology will merely reveal the potential inherent in nature.

These and other antinomies are commonplace in discussions of the impact of biotechnology on farming and food production. They tend to polarize the participants in the debate, though not all participants can be found on the same side of each antinomy. In fact, each of us can be found on both sides of the debate at different points in time. This position is representative of recent developments in the social studies of science. See, for example, Latour (1988) and Busch, Lacy, Burkhardt, and Lacy (1990). Rather than attempting to place myself on one or the other sides in these antinomies, or, alternatively, trying to arrive at some sort of compromise between the two, I wish to begin instead by asking the question: What is it about technical change that gives it this dual appearance? Why does technology appear on the one hand to be the result of deliberate human endeavor and on the other hand the revealing of nature's grand design? Why does it appear on one hand to be the result of heated debate and on the other the irresistible working out of a grand Hegelian plan?

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Let us begin by considering the work of plant breeders. Plant breeders, according to textbook definitions, would appear to be engaged in the process of modifying the genetic makeup of plants within the constraints of Mendelian genetics. But that is only part of the work of breeders. In addition, they perform another kind of equally important work—work that is essential if their discipline is to succeed. What breeders also do is to change the behavior of farmers, processors, wholesalers, retailers, and consumers. In short, plant breeders are responsible for changing human behavior.

Now at first this may appear absurd. After all, we have been brought up to think that it is sociologists, psychologists, or perhaps advertising agents who change people's behavior. However, consider what it means to be a good plant breeder. First, a good plant breeder amasses a wide range of promising materials from all over the world. A good breeder knows the material with which he or she works very well. This kind of knowledge is essential since only someone who knows the material well can pick out the anomalies, the mutations, the extraordinary from the mass of materials that have been collected. Then, the breeder selects only those materials that contain the character(s) of interest which are crossed with other plants to produce a new cultivar. Once the cultivar is produced, we are told that it is simply the best that nature could offer. All the work, all the effort made over several years, is incorporated into the new seed, but it is no longer visible. The new seed looks to all much like the older seeds that have been around for some time. Yet, it contains within it new characters that were never put together in that sequence before.

This does not mean that the work of the breeder is complete. Far from it. If so, we would be very proud of the breeder who collected hundreds of jars filled with samples of new cultivars that never went beyond his or her office. No, the good breeder must also get people to use the new varieties. The diffusion models of technical change (e.g., Rogers, 1983) suggest that breeders develop their new varieties without much regard (at least initially) to the needs and interests of farmers, processors, consumers or anyone else outside the scientific community. Yet, if this were the case, it would be the rare, accidental innovation indeed that actually met the wants or needs of some individual or group. To the contrary, the good breeder will be in touch regularly with farmer groups, processor organizations, transporters, and others to find out just what they will find advantageous to them. Therefore, as soon as he or she has a new cultivar to release, there will already be a market for it. Hightower (1973), in his much acclaimed

and much attacked book of nearly twenty years ago, *Hard Tomatoes, Hard Times*, took the diffusion model seriously. Since all the good ideas were to emerge from the heads of clever scientists and be packaged as technologies that would be available to all, he was scandalized by what he saw as the overly close linkages between certain farmers and agribusiness corporations and public sector scientists.

But let us return to our plant breeders. The good plant breeder must necessarily be in touch with a wide range of (potential) constituent groups in order to know just which two or three of the myriad characters for which one could possibly breed should be the object of breeding work. This will involve negotiation, persuasion, and even coercion on the part of the breeder and the constituent groups (Busch, 1980). However, in the final analysis, our good breeder will choose those characters that are of interest to his or her audience: those involved in the production, processing, and consumption of a particular agricultural commodity. In some cases, breeders take into account some clients but not others, leading to disastrous consequences. See, for example, Flora (1986). Other clients are often ignored by virtue of their powerlessness (Friedland, et al., 1981). In so doing, the good breeder will assure that what has been created by breeding will be rapidly and widely adopted as the new industry standard. In short, the good breeder will and must be just as interested in changing the behavior of people as in changing the genetics of plants.

However, the agricultural sector is different from other sectors of the economy in at least two very important ways and these differences make technical change in agriculture very different than technical change in other economic sectors. First, in agriculture research and development are separated from the production of agricultural products. General Electric and AT&T produce nearly all of their technical innovations within their respective companies. Only a handful of farm businesses (e.g., poultry) do their own research and development work. Instead, public sector institutions such as Land-Grant universities and the United States Department of Agriculture (USDA), and increasingly private companies of various sorts, provide nearly all of the desired research and development. When a scientist at General Electric begins to work on a technical change which appears to have no relevance to the firm's products or processes, his or her work is quickly brought under corporate scrutiny (Reich, 1985). Its potential is discussed and analyzed. Market testing might even be performed. In the agricultural sector, input suppliers and public sector scientists perform the research and development for farmers. Private sector

firms can and do engage in product testing on farms. And public sector scientists often test new varieties in on-farm trials. However, farmers and other potential users are usually brought into the process much further down the line and they virtually never have the same interests as the producers of the innovation.

A second difference between the agricultural sector and the rest of the economy is the inelastic character of the demand for most agricultural products. If the cost of production of automobiles or television sets is forced downwards through technical change, there is a compensatory increase in the number of television sets sold. Certain firms may lose out as a result of this technical change, but the total value added within the commodity subsector will actually rise. Within very wide limits this is true for nearly all industrial products. In contrast, with a reduction in the cost of production of agricultural products, there is virtually no change in the quantity demanded. As a result there is a (temporary) glut on the market until some farmers are forced out of business, the remaining farmers increase their market share, and the remaining value added in agriculture is distributed elsewhere—usually off the farm. Thus, public sector agricultural scientists are faced with a very complex ethical decision: Do they not work for any organization directly involved in the production of an agricultural commodity? Their goal is to further the public good, so their loyalty must be divided among all the constituents of a given commodity subsector. Yet, it is almost inevitable that the result of technical change will be the redistribution of wealth and income within that subsector. Boysie Day (1978) has argued that agronomists should be revolutionaries, pushing aside all who would block the technical changes they propose; doubtless, other agricultural scientists would disagree. Ruttan (1982) has argued at length that scientists should not be asked to shoulder too much responsibility for their actions. Nevertheless, even he notes that “When credit is claimed for the productivity growth generated by advances in agricultural technology, responsibility cannot be evaded for the impact on environmental amenities or on the health of workers and consumers” (1982, pp. 13-21). With this rather lengthy but necessary background, let me now turn to agricultural biotechnology. As I noted in my introduction, there are two competing views that may be taken of the new biotechnologies. On the one hand, it may be argued that biotechnology is much like other technical change. Its consequences will be little different from what has already been experienced. On the other hand, it may be argued that biotechnology represents a qualitative shift in the process of

technical change in agriculture. I shall not argue for one or the other position here. Instead, I wish to argue that both positions are in some sense right.

### **Biotechnology Is Like Other Technical Change**

Biotechnology will probably have less impact on the total number of farms than previous mechanical and chemical technologies adopted by farmers during the last 50 years (Buttel, 1989). This is the case simply because the overwhelming majority of farms that once existed in the United States are now no longer in existence. The largest 13 percent of farms now produce over 75 percent of the value of total production. The rate of increase is bound to slow as we approach 100 percent. With only two percent of

**In short, biotechnology will not exacerbate the decline in the number of farms, though it will certainly continue present trends.**

the population on farms, the cost of replacing more people with capital will be far greater than it was in the past. In addition, the vast majority of small farms are now buffered from the effects of technical change by the fact that farm income is no longer the primary source of income for their owners. Thus, irrespective of the changes wrought through biotechnology, small farms are likely to continue to exist. In short, biotechnology will not exacerbate the decline in the number of farms, though it will certainly continue present trends.

Biotechnology will certainly continue to produce labor saving farm level technologies. This has little to do with the total amount of labor available. It has to do with the fact that labor control on the farm has always been and will continue to be a source of difficulty for farmers (Friedland, et al., 1981). Farmworkers, on the other hand, have rarely enjoyed access to research laboratories and, in any case, are not the purchasers of the new technologies. However, this is only a continuation of a long, well-established (though not necessarily morally justified, end substituting technology for labor in farming (and in most other industries as well)). Social scientists and others in Land-Grant Universities have been concerned for some time about the inattention paid to the problems of farm labor. See, for example, Cargill and Rossmiller (1969), Friedland (1984), and Coye (1984). On the other hand, biotechnology will probably also create some new high technology jobs in the farm input and food processing sectors. The factory setting in these industries makes labor control much easier. Again, the same could, and has been said, about older mechanical and chemical technologies.

**Biotechnology will increase the value-added off-farm at the expense of value-added on-farm.**

Biotechnology will also continue to reduce production costs. This, as with any new technology is an essential component—though certainly not the only one—in its adoption. Thus, we can expect biotechnology to cut further both on-farm and off-farm agricultural production costs. However, the impact on consumers is likely to be greatest for off-farm cost reductions as the on-farm component is now a negligible percentage of the total cost of food and fiber.

Biotechnology will increase the value-added off-farm at the expense of value-added on-farm. Here again, this is an old pattern of technical change, due in large part to the inelastic demand for farm products as noted above. However, since most value is now added off-farm, new biotechnologies will likely have less effect than the older mechanical and chemical technologies. In short, as Goodman, et al., (1987) have argued, the new biotechnologies will further both appropriation and substitution. On the one hand, they will further appropriation by continuing to remove certain processes from the farm and inserting them into industrial production (e.g., the removal of butter processing from the farm to the factory). On the other hand, they will further substitution by creating whole new processes (e.g., the substitution of margarine for butter). In these senses, the new biotechnologies do not represent a significant change; they are merely more of the same.

### **Biotechnology Is Unlike Other Forms of Technical Change.**

Yet, at the same time, we may argue that biotechnology is quite unlike other forms of technical change that have affected the agricultural sector. First, biotechnology will bypass the Extension Services. Previous forms of biological research have been marketed through the Extension Service. New seeds may often have been produced by private seed companies, but the Cooperative Extension Service has played the role of telling farmers what seeds would do best in given climates and soils. The creation of seed-chemical packages puts together decisions previously made serially. Extension has been skillful in recommending specific incremental changes in products and practices, but it has never been able to distinguish between various combinations of inputs and practices. This has always been left to the farmer. Hanway (1978, p. 5) has noted that "Up to the present time we have not really developed comprehensive, integrated, multidisciplinary research programs that deal with improvement of crop production systems as systems.... In the United States most individual compo-

**Biotechnology will** nents are studied independently of others. Recommendations and educational efforts are carried out by specialists each traveling his own way and telling

his own story. The farmer is confronted with making a system out of all the diverse information that comes his way. I'm sure experiment stations have not often assembled all the components of the systems they recommend to see how they function together." In fact, in many states Extension no longer has the expertise (when compared to farmers) even to carry out its old mission; evaluation of packages is a task for which Extension is totally unprepared. Moreover, since the new packages will not emerge from Land-Grant research, public sector scientists will have little knowledge with which to support Extension programs. In short, the evaluation of the various packages will require skills that surpass those in the Extension Service. Given the current funding shortfalls in Extension, it is unlikely that this problem will be remedied. More likely, Extension will (not so) gradually be reduced to playing a secondary role in farm change.

Biotechnology will also accelerate the trend toward contract integration. Already, commodities such as poultry and most processing vegetables are produced on contract. Such contracts specify the seeds, chemicals, planting and harvesting times, and other aspects of farm production.

**A third change that is on the horizon as a result of the new biotechnologies is an increase in the number of market niches in farming.**

Some have argued that farmers who produce on contract are best viewed as employees of the contracting company as their role in decision making has been so reduced as to eliminate their autonomy (e.g., Heffernan, 1984). Through the development of functional attribute crops, biotechnology will speed the push toward contract production into other commodities

(Moshy, 1986). It will also increase the importance of precision in planting, growing, and harvesting crops in order to fit certain markets. This will further reduce the autonomy of farmers and will most certainly reduce their contacts with and needs for Cooperative Extension.

A third change that is on the horizon as a result of the new biotechnologies is an increase in the number of market niches in farming. Functional attribute crops, already noted above, will make it possible to produce special grains for starch production, crops designed for the production of plastics (e.g., Pool, 1989), and other yet to be invented specialty crops. This differentiation within farming will actually reverse the long

trend toward dedifferentiation within agriculture. However, it will not merely involve the return to some earlier time. Consider a crop like wheat. One hundred years ago wheats varied enormously in quality, yield, color, texture, etc. Over the last century, largely as a result of breeding combined with product standards, there are not only fewer wheat cultivars, but also far less variation in the quality of wheat products. This homogenization of wheat has been advantageous to some in that it made it possible to trade internationally in wheat without seeing the product before delivery. It also virtually eliminated poor quality bread from the market. On the other hand, it is unlikely that consumers ever wanted white pan bread with the startling uniformity it had for more than half a century in the United States (Giedion, 1975). This said, the new biotechnologies offer the possibility of specialized wheats designed for use in the manufacture of specific

**.. the entry of molecular biology into agricultural research has been accompanied by the insertion of the agribusiness sector between farmers and researchers.**

food products as well as for industrial uses (e.g., Austin, 1986). These new market niches will involve the proliferation of standards rather than a return to the situation of 100 years ago when standards did not exist.

The new biotechnologies will also restructure the relations between farmers and researchers. Until very recently, farmers were seen as the primary clientele for public sector research. However, the entry of molecular

biology into agricultural research has been accompanied by the insertion of the agribusiness sector between farmers and researchers. The Rockefeller Foundation report (1982) and the National Research Initiative have supported a move to what is commonly called basic research. Agriculture, and particularly the plant sciences, have suffered from a lack of attention to fundamental questions. However, the National Association of State Universities and Land-Grant Colleges has noted a considerable decline in the numbers of plant and animal breeders employed at Land-Grant Universities (NASULGC, 1989). It is apparent that most of these positions have been filled with molecular biologists. Breeders have traditionally seen their prime clientele in the farm population. Farmers often visit breeders to make specific requests of them. In contrast, much of the work of molecular biologists only benefits farmers (to the extent that it benefits them at all) by contributing to the product development work in the private sector. As a result it is quite possible—indeed, likely—that certain problems not of interest to the agribusiness sector will not be the subject of public research either.



The new biotechnologies also have within them the potential to change the very nature of food itself. In the past, the ability of scientists to alter food has been limited by three factors: First, nearly all genetic change in crop plants has been limited to that which could be achieved through sexual reproduction. Thus, the categories of food plants and animals were grounded in certain natural obstacles that could not be overcome. Now it is possible to move genetic material virtually at will among plants, and between plants, animals, and microorganisms. Second, while it has been possible to mix ingredients from various sources to produce food products for millennia, it was very difficult (and in many cases impossible) to break down food products into their essential components. Now it is possible to consider the production of fabricated foods (e.g., Stanley, 1986) in which basic foods are broken down into their component parts (e.g., starch, fat, sugar) and recombined to make wholly new types of foods. Finally, while human beings were required to raise entire plants and animals in order to obtain the parts that were edible or useful, we are now on the verge of being able to produce just those plant or animal parts we desire *in vitro* (Rogoff and Rawlins, 1987). Already, Imperial Chemical Industries (ICI) has managed to synthesize vanilla *in vitro* (Bock and Marsh, 1988). That product will be cheaper than vanilla from vanilla beans but more expensive than the artificial vanilla currently available. Its use now hinges on whether or when the Food and Drug Administration (FDA) will grant ICI the right to call the new product "natural vanilla." I shall refrain here from speculating as to the short- or long-term consequences of such a restructuring and industrializing of the food supply (but see Busch, 1990). Suffice it to say that such new forms of food will make it far more difficult for the consumer to obtain a balanced diet than at present. It will also make food production more and more like the production of other manufactured goods.

Last, the new biotechnologies will increase the possibility of what Charles Perrow (1984) has called normal accidents through tight coupling. Until very recently, foods have been adulterated only by virtue of deliberate human decisions. In some cases, adulteration was the result of adding things to food (e.g., watering down milk), while in other cases it was the result of neglecting to take necessary precautions in processing. Our pure food and drug laws were passed with those notions in mind. However, the new biotechnologies raise yet another possibility: that the increasing complexification of food production, the creation of more and more complex systems in which food passes near potentially harmful sub-

stances, raises the possibility of accidental contamination that is not due to any human decision but to the complexity of the systems themselves.

### **Conclusions: Research For What and For Whom?**

In short, the very fact that the new biotechnologies have to date had very little effect on farming or food production makes it possible to argue both sides of the case. Consider the case of the gasoline-powered farm tractor. When initially introduced it was the subject of raging debate among farmers and scientists alike. Would it replace the horse and ox? Would it transform world agriculture? Now, with the advantage of 20/20 hindsight we can argue that the triumph of the gasoline powered tractor was certain. It had the necessary flexibility, it did not require feeding all through the winter like a horse, and it was lighter than steam tractors and therefore not as likely to get bogged down in the mud. In other words, the gasoline tractor was an inevitable step on the path to progress.

However, to do that is to forget the powerful interests that lined up behind the tractor and those that eventually abandoned the horse and the steam tractor. These interests that built repair shops and gasoline distributorships, that permitted and even encouraged bank loans to farmers who wanted to buy tractors, and restructured rural society so as make it more amenable to tractor production helped to create the "inevitability" that the tractor had. And, at the same time, the tractor itself was changed considerably (Sahal, 1981). The iron wheels were replaced first with hard rubber and then with balloon tires permitting greater buoyancy in the field and less soil compaction. The power takeoff was added, permitting the tractor to engage in a wide variety of work far beyond what a horse could do by dragging a plow.

The situation for the new biotechnologies today is much the same as it was for the tractor at its inception. Strong claims on all sides are the order of the day. Yet, the outcome is quite unclear. It is conceivable that certain biotechnologies will go unused because certain groups see them as too dangerous, as a violation of deeply held values, or less desirable than other existing alternatives. It is equally conceivable that the new biotechnologies will push aside existing technology and social relations and transform society once again. Only in half a century will the "inevitability" of the process become apparent.

In the meantime we who are in the public sector, who are paid by the public purse, need to ask the tough questions that proponents of these and other technologies will not and need not ask: What will be the ben-

efits of the new technologies? Which of them do we need and want? What limits do we want to put on their development and use? Who will benefit from these new technologies? Will the benefits and costs be equally distributed, or will some benefit while others bear the costs? How much power do we want to have over the natural world? Do we have the wisdom to know what to do with that power once we have it?

Technology is a human creation. It is not a matter of whether its development shall be controlled, but who shall control it? Shall it be developed to serve narrow vested interests or broad public goods? Shall it serve to reinforce widely held values or to shatter them? As I noted above, scientists always do double work: They at once modify nature and human behavior and institutions. If that is the case, then scientists have a special obligation to take these questions very seriously, and not to let funding sources, enthusiasm with the power of the new technology (Idhe, 1979), or personal gain or glory permit the avoidance of these difficult questions.

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## Risk: Ethical Issues and Values

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Poets tell us that the locus of value judgments is the heart. Cognitive scientists have told us that it is the brain. I am here to tell you that it is the stomach. Upton Sinclair learned this when he wrote *The Jungle*, intended to expose the appalling conditions under which recent immigrants to the United States were forced to live. Instead, his discussion of slaughter and packing houses in the Midwest spawned the public outcry that initiated our current laws on food safety and quality. The American public's ability to translate a broad range of social and ethical issues into food consumption issues is truly amazing. Criticisms of bovine somatotropin's impact upon economies of scale in dairy production have been translated into concerns about the safety of milk, and animal rightists' protests against production methods for veal calves have been translated into concerns about the human health effects of eating the meat (Browne, 1987, Burton and McBride, 1989).

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The most important ethical value associated with food safety and nutritional quality is human health. Ethical controversies associated with food safety and quality have evolved around the question of when to allow substances into the food chain, and at what levels. The controversy over recombinant bovine somatotropin (BST) appears to raise the same question. The values and decision rules that are applied to the regulation of additives and residues are extremely diverse, and they are not mutually consistent (Halloran, 1986). Part of the diversity and inconsistency arises from competing accounts of health itself (Sagoff, 1985) but this component of the food safety debate will not be discussed

here. There is a pattern of argument in food safety debates that is widespread across policy issues in which scientific evidence is expected to be decisive. The first element of the pattern is criticism of the data, conclusions, or methods that have been used in assembling the scientific evidence. The second element is an inference to the effect that uncertainty in data, conclusions or methods entails risk to members of the public. The final element is an attack upon the motives or values of scientists themselves, who are portrayed as trying to conceal risks and uncertainties from public view (Thompson, 1986).

The public discussion of foods, food additives, and chemical residues produced using techniques of recombinant DNA transfer has yet to move through each phase of this pattern. Nevertheless, the appearance of newspaper articles raising questions about the human health implications of BST would appear to justify the fear that technical solutions to the measurement of human health risk from the products of biotechnology will not resolve the public controversy. If controversial biotechnologies follow the pattern of energy and chemical technologies, ethical values will be interwoven with statements and attitudes about the nature of risk, and with beliefs about evidence and behavior influence risk. Controversy and miscommunication arise to a considerable degree from the public's inability or unwillingness to understand and accept the technical definitions of risk used by the scientific community. This paper will first examine some of the breadth and vagueness in common applications of the word "risk", then will discuss three types of ethical issue that emerge readily from the common grammar of risk, but not from accepted technical concepts.

### **Qualitative and Conceptual Elements of Risk**

**"Risk" is a common English word. It can not be appropriated as a technical term without inviting miscommunication.**

Scientific research techniques are well suited to the measurement of certain key relationships between exposure to a given substance and the subsequent occurrence of harm. These relationships are important in food safety because high correlations between exposure and harm give cause for concern about the human health effects of exposure to the substance.

Though important, the measurable relationships between exposure and harm are misleading policy indicators when they are taken to define risk to the exclusion of qualitative characteristics. One often hears the opinion that scientists study the reality of risk (Starr, et al, 1976; Ruckleshaus, 1983). People who are concerned with other factors relevant to risk are

dealing with mere perception; only the scientists deal with reality. This view of risk is logically insupportable (Thompson, 1990) but what is important here is that it conceals a normative judgment to emphasize the measurable correlations between exposure and harm behind the language of perception and reality. Risk and reality are both politically potent notions. The judgement to emphasize measurable relationships is often justified; taking these relationships to model the reality of risk is not.

"Risk" is a common English word. It cannot be appropriated as a technical term without inviting miscommunication. Careful listening to the way that the word "risk" functions in ordinary speech reveals a varied pattern of use. One variation of particular importance concerns a tendency to use the word risk both as a classifier for acts and as a descriptor of future events. Risk is both a verb and a noun. As a verb, it denotes something that people do. The most common formulations imply intentionality, that is, that when people risk, they do so on purpose (through intentional acts of risk can have unintended consequences). When people run risks they have not consciously taken, the tendency is to shift the word "risk" to its nominative form. Even as a noun, however, risk is ambiguous between its act-classifying and its event-describing meanings. As a classifier of actions, the noun "risk" names those actions that might have been described using the verb form, as in "She risked her life unknowingly by smoking cigarettes." Note that although this act-classifying use of the word does not always imply that a person has knowingly chosen to risk, it does imply that the act in question is an intentional one. We would not, for example, describe an epileptic seizure as "risking one's life," despite the clear indication that there is a significant probability of harm associated with seizures. The reason is that enduring a seizure is not an intentional act. This grammatical pattern allows us to say that, in one sense, enduring a seizure is not a risk, because the seizure is not an intentional act. Calling the seizure a risk in this sense would be a category mistake. The grammar of risk allows "Why do you risk your life by having a cigarette?" but not "Why do you risk your life by having a seizure?"

It is clear, however, that the word "risk" is also used to describe a trait of future events, e.g. that if they occurred they might be harmful. We talk about the risk of an earthquake or a flood, and sometimes even ordinary people say that floods and earthquakes are risks, (though in my experience this form of speech is far more common among risk analysts and scientists). If the word risk is used to describe this trait of events, or if it is used to refer to events having this trait to a strong degree, different grammatical



rules come into play. Since situations such as enduring a seizure are significantly correlated with some probability of harm, they would be clear cases of risk. Indeed, there appear to be no situations that do not involve some degree of risk, at least when it is the event-describing sense of risk that we have in mind. As such, when grammatical rules for act-classifying are applied, an epileptic seizure is not a risk, but when rules for event-describing are applied, it is.

The philosophical grammar that distinguishes these two senses of risk is admittedly subtle (Thompson, 1987a). An epileptic seizure is a risk to one's life, but to have a seizure is not to risk one's life. Simply inverting the word order entails the semantic change. The differences between act-classifying and event-describing uses of risk are not sharp enough to warrant the claim that there are two, fully distinct meanings. Nevertheless, the different uses of the word "risk" suggest opportunities for technical or formal specifications of the term risk that stress event-describing grammar to the exclusion of act-classifying grammar (or vice versa).

The expected value analysis of risk, for example, defines risk as a function of the probability and value (utility) of future events (Friedman and Savage, 1948). Expected values are themselves computed as a function of value or utility associated with the event and the probability of the event's occurrence. There are several ways of representing risk as an expected value. One simple and intuitive function is for all. This concept of risk can be linked to decision-making through the expected utility theory of choice. Although there are several decision rules that can be applied to convert expected utility calculations into action (Rescher, 1983), the simplest one assumes that the objective of decision making is to select the option with optimal expected utility. The option with the highest net expected utility, once costs and benefits are weighed, is the one that should be chosen.

The expected value analysis of risk places a great deal of emphasis upon quantifiable probabilities, plus it is easily linked to a theory of choice. These two factors make it very attractive as a conceptual approach for science-based public policy (Kneese et al., 1983; Freeman and Portney, 1989). The expected value analysis of risk also provides a rigorous and sophisticated development of the event-describing applications of risk that we note in ordinary language. The rigor in the expected value analysis, however, is achieved at the expense of act-classifying shades of meaning that can be detected in the ordinary concept of risk. I suggested above that correlations between exposure and harm are extremely important in setting policy for food safety and quality, but that they do not exhaust the ethically signifi-

cant aspects of risk policy. I shall, in the next three sections of this paper, offer some examples of ethically significant issues that are conceptually linked to the act-classifying grammar of risk.

### **Human Action, Risk, and Responsibility**

As noted above, the expected value analysis of risk applies equally well to intentional actions and natural events. One can quantify the fatality risk of driving drunk, of undergoing a seizure, or of being caught in an earthquake. Simple comparison of the expected values makes these events appear morally commensurate, but they are not. We hold people responsible for their action when they drive drunk, but we do not hold people responsible for the consequences of enduring a seizure or an earthquake. The expected value analysis of risk provides no clue as to whether an agent would be held responsible for their actions, or correlatively, as to whether it would be responsible to act in a prescribed way.

We do not classify the seizure or the earthquake as acts, but drunk driving is an act. The act-classifying rules of grammar for risk are part of a taxonomy for sorting different kinds of action. Some actions are considered risks, others are not. The criteria for sorting seem to involve paradigm cases or ideal type classifications, so that judgments as to whether an act is a risk can be drawn by analogy. In our society, driving while drunk is paradigmatic case of risk; driving while sober is not. It also seems that traditional familiarity with the act in question is a criterion. Using the new fan-gled convection oven is a risk; boiling peas on the stove is not. Here, calling an action a risk is one way of noting that a person will be held responsible for the consequences. It is a way of urging caution, rather than a claim that significant probabilities of harm exist or have been measured.

An idealized depiction of traditional tort law provides the clearest account of how classifying actions under the category of risk plays a role in making decisions and in assessing responsibility. Innovations in the case law of torts during the past two decades have introduced the expected value analysis into liability decisions (Schroeder, 1986), so the following portrayal of torts should not be taken as a description of current practice. Traditional torts are based on common law. The purpose is to assess whether the claimant bringing suit was wrongfully harmed by the defendant, and whether the defendant should be required to pay damages. The claimant may meet his burden of proof by showing that the actions of the accused were risks, then that they actually resulted in harm to the claimant. Simple demonstration of harm is not enough to warrant damage in traditional

torts, for the defendant's act is judged to be a risk only when it is something that a reasonable person would not do. If the act would have been regarded as unexceptional and proper by a reasonable person, the claimant cannot meet the initial burden of proof. The principle implies a general recognition that harm can occur as a result of happenstance, freak events or so-called acts of God, even when the actions of a defendant are completely ordinary acts of the sort that reasonable people perform everyday. Even when the claimant meets the dual burden of proof, the defendant has an opportunity to demonstrate exculpatory factors, and the list of potential exculpatory factors is extensive. They include, for example, whether the defendant acted knowingly and whether the claimant had complicity in undertaking the risky course of action.

The key concept in proving both the initial claim of risk and in providing excuses is that of the reasonable person. In the traditional process of establishing responsibility, there is a large class of actions that are not risks, simply because they are so broadly accepted, even though there are measurable (and perhaps even relatively high) numerical probabilities that they might result in harm. As is generally the practice in common law, criteria for deciding what is a risk and what is not are established by drawing analogies to precedents. These criteria are set forth in judicial opinions and become more deeply embedded into law the longer they endure, and the more broadly they are applied (see Thomson, 1986 for a general discussion of risk in tort law). Laws regulating food safety are statutory and administrative, so the traditional practice of torts may be a poor model. The point is not to advocate reliance upon traditional case law, but to show how this idealization of torts draws upon the act classifying grammar of risk in making a determination of responsibility.

From a policy standpoint, the principal advantages of stressing the act classifying sense of risk arise from its power to link harm with actions for which persons could be held legally or morally responsible. The expected value analysis, by contrast, stresses the sense in which every instance of harm falls into statistical patterns. Since individual persons or corporate groups are clearly not responsible for the statistical pattern, this can make it seem as if they should not be held responsible for the harm that does materialize as a result of their actions.

### **Equivocation Problems and False Authority**

Equivocation upon distinct meanings of the same term is one of the most egregious and indisputably fallacious forms of logical error. Although

equivocation fallacies are conspicuous when exposed, their obviousness does not preclude their occurrence. Equivocation has ethical implications when it is the source of error in judgment, or in communication. Equivocation can also play a role in the creation of false authority, as when a judgment justifiable on one interpretation of the term is imposed upon a situation in which the alternative interpretation would be more appropriate. More serious ethical issues arise when equivocation is used as a deliberate vehicle of deception.

Although simple errors of judgment and intentional deceptions occur in the discussion of food safety literature, false authority may be the most important ethical issue associated with equivocation on the act-classifying and the event-describing meanings of risk. Most people apply the concept of risk in ordinary decision making without being fully aware of the semantic content or logical structure of either act-classifying or event-describing usage. The context of speech is usually sufficient to specify the meaning intended in any given speaker's utterance. If the application of risk concepts implied in each usage were to be specified rigidly, as in the expected value analysis of risk, the result would be two incompatible concepts of risk. The problem of false authority arises when the expected value analysis of risk is applied in such a way as to make otherwise reasonable judgments appear illogical, uninformed, and even irrational.

**Acceptability, in other words, implies an intentional attitude toward the act, not mere tolerance on passively enduring a state of affairs.. It may indeed be a foolish waste of public resources to ensure against harms that are already far less likely to occur than harmful natural events.**

One instance of the false authority fallacy occurs when actions for which individual or corporate agents can be held responsible are compared to natural events in order to derive standards for acceptable risk (Starr, 1969). Many naturally occurring substances are estimated to possess greater carcinogenicity than heavily banned additives and heavily regulated chemical residues (Ames 1983). What should we make of this fact? The expected value analysis of risk can be interpreted to imply that there are certain trade-offs between risk and benefit that are acceptable, without regard to the

origin of the risks. The preceding discussion of responsibility shows that origins are sometimes important. Although it is clear that the dangers of natural carcinogens have been tolerated or endured by human populations, the expected value analysis of risk begs the question of why we should tolerate or endure similar levels of expected harm from human action (Thompson, 1987b).

When responsibility is important, the permissibility of risk is determined by comparing the act to the standard range of things that human beings do, by considering the importance of the ends sought, and by examining the alternative ways of achieving the end. In this context, the judgment that a risk is acceptable implies that there are overriding moral or prudential reasons for acting in an exceptional manner. Acceptability, in other words, implies an intentional attitude toward the act, not mere tolerance on passively enduring a state of affairs. There is a genuine philosophical issue here. It may indeed be a foolish waste of public resources to ensure against harms that are already far less likely to occur than harmful natural events. The important philosophical issue is not illuminated, however, when the expected value analysis is falsely applied to cases where human agency and responsibility for risk are clearly important.

There may also be elements of equivocation in the so-called "zero risk" debate. When the concept of risk implies a classification of actions, the main point is to use case analogies and the vague notion of a reasonable person to classify an act as risky or non-risky. As noted above, some situations get classified as "no risk" for reasons that have nothing to do with probability, but everything to do with the grammatical rules for act classification. The rules for a "no risk" classification depend upon analogies to unexceptional, ordinary things that any reasonable person might do, as well as to whether the event in question is an intentional act. It is possible, for example, to adopt an act-classifying standard of zero tolerance for risk. The standard prohibits any intentional action that risks health and safety of others. This standard does not imply, however, that there is zero probability of harm for the category of risk may exclude both traditional practices and natural events. Under an expected value interpretation, risk can be zero only when the probability of an event is zero; but it is impossible to reach absolute zero probability using standard statistical techniques. At face value, the Delaney Clause appears to be a zero tolerance statute, and the "generally regarded as safe" (GRAS) list would appear to reflect the reasonable person's judgment of what is and is not a risk. The regulatory interpretation of the Delaney Clause has come to be understood as requiring zero probability of harm, however. If one applies an expected value criterion to the act-classifying standard of zero tolerance, the standard becomes absurd (NRC, 1987). Any situation can be statistically correlated to harmful events! How the Delaney Clause should be interpreted is a serious philosophical issue, but the serious issue is concealed by the law's apparent absurdity, given an expected value analysis of risk.

The problem of false authority relates to the role of science in the policy making process. There are always good scientific reasons for adopting the expected value analysis of risk, and there are sometimes good policy reasons too. When the expected value analysis comes to exclude the multiple shades of meaning that are associated with risk in common speech, however, some of the most natural ways of raising serious issues about responsibility for action appear absurd. People who are applying the grammar of risk in very standard and traditional ways appear to be making logically insupportable statements, and the ethical issues that would be raised by these standard and traditional ways of talking about risk appear chimerical and irrational. The danger is that the appearance of irrationality will be dealt with by handing policy over to experts; only in this case, the criterion for being an expert lies primarily in possessing an impoverished understanding of risk.

### **Optimizing Versus Informed Consent**

So far, the main implications of noting the act-classifying sense of risk have been rhetorical. One should be careful not use the word risk in ways which preclude or diminish the validity of responsibility issues, and one should be careful not to imply false authority by equivocating on act classifying and event describing senses of the word. The last set of implications are more substantial, and less easily resolvable. The expected value analysis of risk fits neatly with a general philosophical commitment to the view that policy should be evaluated according to whether it makes an optimal use of public resources in providing benefits to citizens. This broadly utilitarian view of public policy has long been challenged by opponents who stress consent of the governed. The opponents of utilitarianism hold that government action is legitimate when it is the result of procedures designed to secure or reflect the consent of all who are affected. In many cases these two principles will coincide, but there are no logical entailment relations between them, and there are important issues on which they fail to coincide.

The contrast between optimizing and informed consent is particularly relevant for evaluating questions of risk (MacLean, 1986). Within the area of human health risks, we find a stark contrast between risk policies that seek efficient or optimal levels of public exposure to risk, and those that stress informed consent. Both strategies for assessing and accepting risk are enormously complex in their details. Optimizing, as I use the term here, includes any strategy that applies a threshold or benefit-risk decision

rule to a measured risk, though the application of alternative decision rules can result in very different risk decisions. Regulatory policies administered by the Environmental Protection Agency (EPA) are a clear example of the optimizing strategy. Consent policies can delegate decisions that might have been made by public agencies to the private sector, and this strategy can make it appear that there is no risk policy in place, at all. For example, our policy of allowing choices on accepting the risks of specific disease therapies to be made on the basis of individual doctor-patient relationships is an application of informed consent. The principle of informed consent places the greatest burden of proof upon parties who are active. In standard health care relationships, the active parties are the physician and the patient. If government were to become active in this policy arena, it, too, would have to meet a test of informed consent.

The main point here is to see how the philosophical conflict between optimizing and informed consent occurs in controversies over food and health policy. The continuing controversy over whether and what public health recommendations should be made regarding dietary cholesterol has an element of this conflict. Public health scientists want strong dietary recommendations, for they think that dietary changes will save lives. Others have opposed general dietary recommendations on the ground that, since some (perhaps many) individuals do not need to follow the recommendations, they are deprived of their right to informed choice when given misleading information by public health authorities (Levine, 1986; Kunkel and Thompson, 1988).

The politics of the FDA's attempt to ban substances such as DES or saccharin have also become entangled in the optimizing/informed consent dispute, with neither the optimizers (Rodricks, 1986; Schultz, 1986) nor the advocates of consent (Turner, 1986; Whelan and Havender, 1986), happy with the result. Citing the DES case extensively, Deborah Johnson (1986) has marshalled some of the principal arguments against consent, at least for food safety and quality. She notes that principles of informed consent presume that food consumers are competent judges of food safety and quality, that they have and can interpret all of the relevant information, and that they are not coerced into making one food choice rather than another. Johnson contends that all of these conditions are, to some degree, unfulfilled. As such, she argues, we are forced to develop decision rules for acceptable risk, though she cautions against a too simplistic application of benefit-risk analysis.

Taking the side of consent, Henry Shue (1986) rejects optimizing policy criteria and risk/benefit analysis in particular. Shue thinks that risk policy should be understood as part of governments general responsibility to protect individuals from harm by others. Optimizing strategies tend to conceal the link between risk and harm. He writes that optimizing policies are “.. ,non-starter[s] because ... the numbers of people count, while in matters of rights, the numbers do not ordinarily count. On the contrary, one of the central purposes of rights is to protect the vulnerable, even if they are a small minority.” (p. 195) It is only when people have clearly chosen to accept risks that they can be understood to be acceptable.

Informed consent is only loosely related to the act classifying sense of risk, for it is clearly possible to raise questions about consent when risk is understood purely as the probability of harm. There is a tendency, however, for optimizers to gravitate toward the expected value analysis as a way to compare risk with other forms of cost and benefit. Similarly, there may be a greater tendency for questions of informed consent to arise when risk is more transparently taken to be a form of action. One way to discharge one's responsibility in taking risks is to ensure that all parties who are affected have agreed to hold the agent blameless.

**Risk is not a real entity or relation that yields its secrets to objective scientific analysis.**

## Conclusions

My main objective in this paper has been to facilitate food safety debates by pointing out some key sources of miscommunication. Risk is not a real entity or relation that yields its secrets to objective scientific analysis. There are philosophical choices to make about whether to regard risk as primarily a taxonomic concept, for which probability considerations are secondary, or to regard risk as a purely statistical concept. Committing oneself wholly to either option has moral and policy implications that are of tremendous significance.

I would not suggest that insupportable food safety judgments, the public concerns about BST, for example, are any sense justified by the ethical values implied in emphasizing action. They are still silly concerns. Understanding risk as a type of action, rather than as a probability of harm, does indicate a thread of rationality, however. The raising of non-food related concerns about BST may have made the introduction of this technology seem less standard and unexceptional than it might have been. Having been categorized as a risk to the economic well being of dairy farmers, it is



**It is scientists who will have to demonstrate insight and sensitivity to the non-quantitative factors that inform policy decisions on risk.**

subjected to much more rigorous conceptual tests than it might otherwise have been. One of these tests is avoidability, whether there is a reasonable alternative. In the case of milk production, there surely is.

There are still some logical fallacies in the chain of reasoning that I have just described, but they are certainly less egregious than simply leaping from the

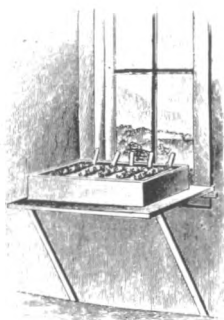
claim that BST may harm the interests of some small farmers to the claim that milk produced with the technology is hazardous to drink. We will, I think, get farther with people who commit such fallacies if we can understand how a reasonable person could arrive at such conclusions than we will by accusing them of emotionalism, fear and irrationality. It is not, however, philosophers who will be called upon to communicate with the public about such risk questions. It is scientists who will have to expose the fallacies with gentleness and tact. It is scientists who will have to demonstrate insight and sensitivity to the non-quantitative factors that inform policy decisions on risk. Rigid adherence to an expected utility analysis of risk will make the scientist's task far more difficult, at least, and may preclude their completing it altogether.

Finally, scientific evidence will not always be the appropriate basis for risk decisions. Sometimes it may be possible and better simply to let people choose the risks they want to take, without even collecting the scientific evidence correlating exposure and harm. Sometimes it may even be better to allow responsibility for risk exposure to be determined in the courts. We currently make huge financial investments in risk assessment, and the scientific assessment of the probability for harmful consequences from biotechnology could cost many times more. Once we have invested heavily in the expected value analysis (both in money and time) it will be hard to ignore the scientific evidence, even if it is inconclusive and irrelevant. There are, in other words, philosophical choices that must be made on the first day of inquiry. Investment in the acquisition of facts has policy implications. In this sense, public policy does not recognize the fact/value distinction. The research and development choices that are made today must be made against a broad, cosmopolitan understanding of the values relevant to food safety and quality. It is, perhaps, the public's confidence in scientific decision makers to faithfully represent the full tapestry of values that will ultimately matter the most. Any tendency to disavow or ignore questions of responsibility for risk will undercut that confidence, and justifiably so.

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## Agricultural Biotechnology, Food Safety and Nutritional Quality for the Consumer